Masarykův onkologický ústav

Poskytovatel zdravotních služeb akreditovaný Organizací evropských onkologických ústavů (OECI) a Českou společností pro akreditaci ve zdravotnictví.

Žlutý kopec 7, 656 53 Brno
Česká republika

PATIENT´S INFORMED CONSENT FORM

with the provision of data within the study ProstaPilot - prostate cancer screening using MRI with an abbreviated protocol (hereinafter referred to as the „Research Project")

Dear Sir,

We invite you to take part in the Research Project focused on the preventive examination of prostate in asymptomatic men. Your participation in the Research Project is voluntary. Your decision to cancel your participation in this project shall not affect the healthcare provided to you nor your relationships with physicians or other healthcare professionals. You may withdraw your consent to participate in the Research Project at any time and without giving any reason.

What is a subject of the Research Project?

For your information, malignant tumors (carcinoma) of prostate can be clinically significant (likely to affect the quality and length of life) or clinically insignificant (without any influence on the length and quality of life even in case it is not being treated). In current practice, a preventive PSA testing (Prostate-Specific Antigen) in serum, provided by general practitioners and urologists, results in the detection of both clinically significant and insignificant prostate carcinomas. Clinically insignificant carcinomas are present in up to 30 % of men over 50 years old and unfortunately represent mainly psychological burden for its carriers. Our working hypothesis, supported by similar British study IP1-PROSTAGRAM and many others, states that with using of magnetic resonance we should be able to search for larger number, especially clinically significant tumors.

What can you expect?

During your participation in this Research Project, a blood sample will be taken for laboratory testing (e.g. PSA). In addition to this established practice, a 15-minute MRI examination will be performed at the CEITEC, organisational unit of Masaryk University. This imaging method does not use ionizing radiation, no contrast agent will be injected into a vein and no unregistered medicaments will be used. The MRI examination which is not ordinarily being made in preventive healthcare, will be performed in addition and its goal is to detect and recognize clinically significant tumors.

In the case of a negative result after the examinations, you will be informed by SMS message. In the case of finding a suspicious tumor or high PSA value, you will be contacted by phone and the biopsy (tissue sampling) will be recommended to you in order to reliably determine whether it really is a tumor. In the case of clinically insignificant tumor, you will be also contacted by phone and appropriate care or follow-up procedure will be offered to you. You should be aware that this can happen also in your case. At the same time, you should be aware that the sensitivity of detecting a tumor by MRI is not 100 % as with any medical method. According to the current information, approximately 5% (1 of 20) of significant tumors will not be detected by this procedure. Depending on the results of examinations, we can offer their repetition after 24 months. Anyway, if a malignant tumor is suspected during any examinations, the following treatment procedure will correspond to the guidelines established in Masaryk Memorial Cancer Institute („MMCI"). The data collection will not influence your treatment. If you wish, you will be observed and/or treated in our Institute according to the standard clinical practice and to decisions of your physician.

The imaging data will be sent from the CEITEC to the MMCI in a secured way (in the same way as all other patients´data are sent). The MRI examination will be evaluated by an experienced physician of the MMCI that enter the result into an electronic register under your unique numeric code (ID). Similarly the authorised datamanager will enter your personal data from your medical records to the electronic register. Only your physician and datamanager will be able to identify you in the register from your unique code (ID) by using key which enables to link unique numeric code (ID) to your personal data. This key is held only by your physician or authorised datamanager. No third person with access to the register will be able to identify you. The access to the electronic register is not public. The access is enabled only to the authorised personnel of IBA (Institute of Biostatistics and Analysis ltd.), CEITEC and IBA LF (Institute of Biostatistics and Analysis of Faculty of Medicine of Masaryk University) who participate in the Research Project and to the employees of controller (MMCI), specifically to physicians or datamanagers in case of data entry, based on approved access rights. The results obtained during

the Research Project will be published anonymously in the aggregated form for large group of patients, not specifically for you personally, not even under your unique ID. All published outcomes **will be fully anonymous (anonymised)** e.g. no third party will be able to identify you based on them.

In order to carry out this Research Project, it may be necessary to access your health data collected in the National Health Information System (NZIS) administered by the Institute of Health Information and Statistics (for example National Cancer Registry, National Register of Reimbursed Health Services), where the health data is collected based on the Act on Health Services. The access is required to verify whether a prostate carcinoma has not occurred after some time when you will no longer be in the care of the MMCI. This information will not be part of medical records in MMCI. Your consent to access your health data in the NHIS is needed because without it we are not authorised to process such data for the Research Project purposes.

INFORMATION BY CONTROLLER FOR DATA SUBJECT REGARDING PROCESSING OF PERSONAL DATA IN RESEARCH PROJECT

CONTROLLER			
NAME	***Masaryk Memorial Cancer Institute***		
REGISTERED SEAT	***Žlutý kopec 7, 656 53 Brno***	ID	***00209805***
CONTACT PERSON/PROFESSION	***Data Protection Officer***		
CONTACT INFO	***Email:dpo@mou.cz***		

DATA SUBJECT	
NAME AND SURNAME	
DATE OF BIRTH	
PERMIT RESIDENCE	

In accordance with art. 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (hereinafter referred to as the "GDPR") we inform you on processing and protection of your personal data e.g. mainly your clinical, diagnostic and lab data gained during Research Project. The purpose of Research Project is summary scientific assessment of methods of preventive examination focused on capture of prostate tumor.

Masaryk Memorial Cancer Institute („MMCI") is controller of your personal data which it has gained or will gain from you for in order to carry out Research Project. Controller processes your personal data only to the necessary extent:

Purpose of processing personal data in Research Project is:

- Analytic evaluation of the reliability of MRI examination for detection of clinically significant prostate carcinoma in asymptomatic men in comparison with the established laboratory methods (PSA tests in serum),
- Scientific and statistical investigation pursuant to abovementioned goal with possibility of outcomes mainly in form of scientific publications, statistical reports and analyses, eventually data sharing with other registers at the national and international level, respectively.

Types of Personal Data Processed in Research Project:	Legal basis for processing:
▪ *year of birth, healthcare provider* ▪ *data on health status, diagnostics and treatment, imaging data from MRI* ▪ *health data collected in National Health Information System*	▪ *art 6 (1.f) GDPR processing is necessary for legitimate purposes of controller, specifically for conducting scientific research focused on oncology – collection, processing, analysis of data (for systematic development of science and research (not only) in MMCI* ▪ *art. 9 (2.j) GDPR for statistical purposes, for scientific research purposes* ▪ *art. 6 (1.a) a čl. 9 (2.a) GDPR based on explicit consent of data subject*

Additional information:

Except for personal data collected in the NHIS (see above) it is not necessary for you to give us explicit consent with processing of personal data because your personal data are processed based on other legal bases listed in the table above. Your personal data will always be handled in accordance with legal acts, mainly Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC and Act No. 110/2019 Coll., On Processing of Personal Data, as amended. **Information about your rights and their application, on specific processing of personal data and other facts related to the processing of your personal data is publicly available on MMCI website (www.mou.cz) in section GDPR and Personal Data Protection.**

The personal data processing is regulated by internal regulations. Personal data is kept in paper (manual) form / electronic (automatic) form. Automated-decision making, including profiling which could have an impact on your rights is not carried out during the automatic processing of your personal data.

You will not be entitled to any remuneration or compensation in connection with your participation in this Research Project.

Resources of personal data

Controller gained your personal data for Research Project from you and also from:

- medical records maintained by MMCI
- imaging data from MRI examination at the CEITEC, Masaryk University, Brno
- data from National Health Information Systems administered by Institute of Health Information and Statistics of Czech Republic

Personal data receivers:

Controller will provide personal data to:

Institut biostatistiky a analýz, s.r.o., ID: 02784114, with registered seat at Poštovská 68/3, 602 00 Brno, registered in commercial registry led by Regional Court in Brno, sp. zn. C 82448 (hereinafter as „***IBA***"), data will be processed only by authorised personell

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Masaryk University, ID: 00216224, with registered seat at Kamenice 753/5, 625 00 Brno (herinafter as „***MU***", eventually its units „***CEITEC***" a „***IBA LF***"), data will be processed only by authorised personell.

Internal receivers: controller will process your personal data only by authorised employees. Patient´s personal data may be transferred only in anonymised form abroad or to international research organisation that engage in scientific projects or use them for statistical purposes.

Masarykův onkologický ústav

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Period of storage of personal data:

Period of storage: data will be stored in databases in an unchanged form for 15 years after Research Project is ended.

Your data subject rights

In connection with processing of your personal data during Research Project you have:

- right to request information on categories of personal data being processed, purpose, period, nature of processing and on receivers of your personal data;
- right to request copy of your personal data being processed;
- right to request (when conditions set by relevant legal acts are met) rectification, completing, erasure or restriction of processing regarding your personal data;
- right to object against processing of personal data based on legitimate interest of controller (art. 6/1 f) GDPR) or conducting scientific research (art. 9/2 j) GDPR);
- right to withdraw the consent with processing of personal data collected in National Health Information Systém;
- right to be informed on data breach in case that such breach is likely to result in high risk to your freedom and rights.

I am aware of the fact that abovementioned rights can be applied directly to the controller, e.g. Masaryk Memorial Cancer Institute, eventually to my physician.

You have right to file complaint to supervisor authority in case that you assume that legal acts on processing of personal data are being violated when processing your personal data. You can file complaint to supervisor authority in place of your living, your employment or in place where alleged breach took plase. Czech supervisor authority is Office of Personal Data Protection, Pplk. Sochora 27, 170 00 Praha 7, www.uoou.cz.

In case of other questions regarding processing of your personal data during in Research Project you can contact Data Protection Officer of controller: **dpo@mou.cz .**

I am aware of abovementioned information:

_____ _____

Place and date **Patient´s signature**

PATIENT´S CONSENT WITH PARTICIPATION IN RESEARCH PROJECT, CONSENT WIH PROCESSING OF PERSONAL DATA AND CONSENT WITH ACCESS TO MEDICAL RECORDS, MAKING EXCERPTS AND COPIES

I, the undersigned:

Name, surname of patien:…… ……

Date of birth:…… ……

Declare that I have been informed by physician:

Name, surname ……

Healthcare provider ……

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I hereby grant consent to my participation in clinical study Prostapilot – Prostate cancer screening with use of abbreviated MRI protocol (hereinafter as „Research Project“).

I hereby grant consent to authorised persons to access my medical records kept by healthcare provider on me and also consent to make excerpts or copies of medical records in connection with collection and processing of my clinical data in Research Project.

I hereby grant consent pursuant to art. 6/1 a) and art. 9/2 a) GDPR to the processing of my personal data collected in National Health Information System administered by Institute of Health Information and Statistics of Czech Republic to the extent necessary for the implementation of the Research Project and for 15 years after its completion. I am aware that I can withdraw this consent at anytime. Withdrawal of consent will have no influence on legality of processing of personal data before withdrawal of consent.

I also agree with providing information on my health status after examinations via phone (suspicion on tumor) or via SMS (negative result) on telephone number which is led in my medical documentation.

I declare that I have read whole document and that I have understood it. After having opportunity to pose questions and to ask about anything that I consider as important and after receiving appropriate answers to my questions I declare that I have fully understood the information and explanation and that I consider information provided to me as sufficient. I am not aware of any reasons that would prevent my consent with registration of data. Therefore based on my free will and information provided I voluntarily agree also with retroactive registration of my data in Research Project.

_____ _____

Place and date **Patient´s signature**

I declare that I have provided patient with all necessary information arising from text on first page of the document and that I have fully informed him on the purpose of registry as well as on his rights connected with processing of his (personal) data in this register as is required by ethical and legal norms. Complex information in sense of this consent form was provided by me from the authority of data controller (MMCI).

_____ _____

Place and date **Signature of physician providing info**

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