Appendix No. 1 to Appendix No. 1 to
Regulations of the Bioethics Committee at ICZMP
introduced by Order No. 36/2022 of the Director of ICZMP of 16/05/2022

INFORMED CONSENT OF THE PATIENT AND/OR STATUTORY REPRESENTATIVES TO PARTICIPATE IN A MEDICAL EXPERIMENT AND PROCESSING OF PERSONAL DATA

Title of the medical experiment/research: The use of MET-PET combined with MRI in surgical treatment and postoperative radiotherapy of glioblastoma multiforme - a randomized, blinded, prospective study.

Details of the person referred for testing:

Name:	
Last name:	
PESEL:	☐☐☐☐☐☐☐☐☐☐☐
In the case of a person who does not have a PESEL number - name and number of another document confirming identity:	…… …… ……

***Details of the parent or legal guardian (complete* if *the person referred for testing is a minor)* :**

Name:	
Last name:	
PESEL:	☐☐☐☐☐☐☐☐☐☐☐
In the case of a person who does not have a PESEL number - name and number of another document confirming identity:	…… …… ……

***Data of the second parent or legal guardian (complete* if *the person referred for examination is a minor)* :**

Name:	
Last name:	
PESEL:	☐☐☐☐☐☐☐☐☐☐☐
In the case of a person who does not have a PESEL number - name and number of another document confirming identity:	…… …… ……

(*In the case of minor Participants, it is necessary to express written consent from each of the legal representatives of the minor and their joint consent and:*

- for Participants who are under 13 years of age signed by the child's parents/legal representatives and the child himself, if he is able to understand the information regarding

the examination being conducted. If a child does not consent to the proposed study, he or she cannot participate in the study.
- for Participants who are over 13 years of age and they are under 18 years of age , signed by Participants and parents/legal representatives of the child)

I declare that I have been informed (a) by ……. . about the purpose of the above study, duration, method of conducting it, expected benefits, possible risks and threats, any inconveniences related to participation in this study, and about my rights and obligations.

I declare that I have read and understood the content of the patient information form regarding the described clinical trial and have received comprehensive and satisfactory answers to the questions asked.

I was informed that participation in the medical experiment is voluntary.

I am aware of my right to withdraw from participation in the study (withdraw consent) at any stage, without giving a reason. I have been informed that exercising this right will have no negative legal consequences in the form of any discrimination, including the right to health care, and will not affect the further course of my treatment. I have received a signed and dated copy of this form and a patient information form regarding the study.

I consciously consent to the use of medical records and the collection of biological material (whole blood, a fragment of post-operative material taken as part of medical treatment/procedure, other material, performance of another medical procedure, etc.).

have read the terms and conditions of civil liability insurance for damage caused in connection with conducting the study in accordance with policy no. …….. of …… issued by …… ……., including the rules for paying compensation in the event of damage.

I give my full, informed and voluntary consent to participate in this medical experiment/research.

Patient:

……	……	……..
(name and surname)	(signature)	(date)

Parent/legal guardian:

……	……	……..
(name and surname)	(signature)	(date)

II Parent/legal guardian:

……	…… ……..	
(name and surname)	(signature)	(date)

I, the undersigned, declare that I have explained to the Patient the details of the proposed examination, as described in the patient information form. Before any procedures were undertaken, I discussed with the Patient his/her participation in the entire research program, informing about the goals and nature of the clinical trial as well as the benefits and risks resulting from participation in this study. When talking to the patient, I discussed the presented study using understandable, possibly simple terms and provided explanations regarding the essence and importance of the study.

Person obtaining consent for the study:

.....	…… ……		...
(name and surname)	(signature)	(date)	

INFORMED CONSENT OF THE PATIENT AND/OR STATUTORY REPRESENTATIVES TO THE PROCESSING OF PERSONAL DATA

Title of the medical experiment/research:

The use of MET-PET combined with MRI in surgical treatment and postoperative radiotherapy of glioblastoma multiforme - a randomized, blinded, prospective study.

I consent to the processing of my data

data in this study in accordance with the law in force in Poland (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 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). I consent to the transfer of my anonymous data to other countries, both within and outside Europe. However, the data analyzed by the relevant authorities, representatives of the Ministry of Health, the study sponsor and its representatives, the US Food and Drug Administration (FDA) and other government organizations and bioethics committees will be available only in anonymous form.

I have been informed that:

a. the data controller is the Provincial Multidisciplinary Center of Oncology and Traumatology. M. Kopernika in Łódź (WWCOiT), ul. Pabianicka 62, 93-513 Łódź
b. The Data Protection Inspector at WWCOiT is Mr. Tomasz Zdzienicki , e-mail iod@kopernik.lodz.pl My personal data will be processed for the purpose of carrying out the study *Application of MET-PET combined with MRI in the surgical treatment and postoperative radiotherapy of glioblastoma multiforme - a randomized, blinded, prospective study.*
c. in WWCOiT pursuant to Art. 9 section 2 letter a of the general regulation on the protection of personal data of April 27, 2016.
d. about the method of data processing, the right to access them, submit an application for rectification, deletion, limitation of processing, and the right to lodge a complaint with the Personal Data Protection Office.

I have been informed that if I withdraw my consent to participate in the study, the data collected so far may be used and processed as part of the study database.

Patient:

……	……	……..
(name and surname)	(signature)	(date)

I Parent/legal guardian:

……	……	……..
(name and surname)	(signature)	(date)

II Parent/legal guardian:

……	……	……..
(name and surname)	(signature)	(date)