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Information Sheet and Informed Consent Form for to the processing of personal data in the context of the Prospective Observational Study THE PARTNER STUDY. AN INTERNATIONAL PERSPECTIVE OBSERVATIONAL STUDY ON PEDIATRIC PATIENTS WITH VERY RARE TUMORS (PARTNER STUDY) pursuant to Regulation (EU) 2016/679 Art 13 of Regulation (EU) 2016/679, General Data Protection Regulation - GDPR

Adult Patient

Vers. 1.0, 09th Oct 2024

Dear Sir/Madam,

It has been proposed to you to participate in the Prospective Observational Study "THE PARTNER STUDY. AN INTERNATIONAL PERSPECTIVE OBSERVATIONAL STUDY ON PEDIATRIC PATIENTS WITH VERY RARE TUMORS".

Title of the Study	**THE PARTNER STUDY. AN INTERNATIONAL PROSPECTIVE OBSERVATIONAL STUDY ON PEDIATRIC PATIENTS WITH VERY RARE TUMORS.**
Protocol code	
Site	
Principal Investigator's name	
Principal Investigator's contact details	

There are very rare tumours (annual incidence of less than 2 per million/children) that can affect children and adolescents. These neoplasms include a wide variety of cancers, some are rare at any age, others are typical in adults but very rare in children. Due to their rarity, studies have so far been scarce and often lack univocal criteria for diagnosis and more information is needed to improve their treatment.

This study aims to collect epidemiological, clinical, biological, radiological and treatment data of children and adolescents with rare cancers, to improve our knowledge of these tumours and try to understand how their clinical and biological characteristics can affect the results of treatments.

Due to the rarity of these malignancies an international collaboration is necessary to collect enough data for each different type of tumor.

In this study, we are not proposing specific treatment but the data that will be collected will help us to develop recommendations for the diagnosis and treatment of patients.

Participation in "THE PARTNER STUDY" will involve the processing of your personal data.

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With this document, pursuant to art. 13 and 14 of EU Regulation 2016/679 (hereinafter for brevity "GDPR"), we provide you with the information necessary to understand how your personal data will be processed, in order to allow you to decide freely and consciously whether or not to consent to such processing in relation to the Study whose data is indicated below.

1. Data Controllers

The Data Controllers of your personal data are:

- Study Sponsor, Hospital - University of Padua *(AOUP), with registered office in via Giustiniani n. 1, 35128 Padua (ITALY), C.F. and VAT number 00349040287, through the UOC Pediatric Oncohematology* which will process your identification and health data;

- CENTER, _____, with registered office in_____; e-mail_____ as Data Controllers

Both of them, will process,as autonomous data controllers, each in the areas of their own competence and in accordance with the responsibilities established by the rules of good clinical practice (Legislative Decree 211/2003) and the legislation on the protection of personal data (GDPR 679/2016 and Legislative Decree 196/2003 as amended by Legislative Decree 101/2018) and the Guidelines for the processing of personal data in the context of clinical trials of medicinal products - 24 July 2008), your personal data, as specified in point 3.

2. Data Protection Officer

The contact details of the Data Protection Officer, pursuant to art. 37 of the GDPR are:

- for the Hospital - University of Padua is: rpd.aopd@aopd.veneto.it

- for Center has appointed a Data Protection Officer (D.P.O.), who can be contacted at the following email address_____@_____

3. Categories of data subject to processing, purposes of processing, legal basis of processing.

The data processed in the context of the “THE PARTNER STUDY” Study are personal data (personal details and contact details), those concerning particular data such as health data, only to the extent that they are indispensable in relation to the objective of the “THE PARTNER STUDY” Study”.

Your personal data that you provide for the purposes described above will be processed on the basis of your express consent, which therefore constitutes the legal basis for making the processing lawful, pursuant to art. 6, par. 1 point a) and point. 9), par. 2 point. a) of the GDPR. The processing of the personal data referred to above is essential for the carrying out of the study "THE PARTNER STUDY": the refusal to provide them will not allow to participate, without prejudice to the fact that participation is absolutely free

and voluntary and any failure to consent to the processing of data will have no impact on the possibility of accessing current and future medical care.

At any time you can decide to revoke the consent and in this case the Investigator will interrupt the Treatment and inform the Promoter. The revocation of consent does not affect the lawfulness of the Data Processing carried out before the revocation itself.

As with your health data, biological samples (blood, urine, cerebrospinal fluid) are also pseudonymized (a technique that allows you to modify and mask the personal and sensitive data of a natural person, in order not to make them directly and easily attributable to the same), will be used for diagnostic characterization as per normal clinical practice.

-Once the study is finished, the samples will be destroyed, unless you agree to the conservation of the samples for 10 years in the presence of specific informed consent (attached to this information sheet). For any subsequent use of the sample for future research, specific consent for such use must be obtained.

We also inform you that during the genetic research on the sample, unexpected information may emerge which will be communicated to you only with your explicit consent which must be expressed

4. Methods of data processing and any recipients or categories of recipients of personal data.

In relation to the aforementioned purposes, the data indicated will be processed (consulted, communicated, collected, managed, destroyed, stored, etc.) using paper or electronic methods, in order to guarantee the security and confidentiality of the data themselves.

The data collected during the study "THE PARTNER STUDY" will be processed (consulted, collected, managed and stored, etc.) by the owners and the relevant authorized and trained personnel, as well as by external companies acting on behalf of the Promoter (e.g.: Contract Research Organization “CRO”), subjects designated by the Promoter as Data Processors pursuant to art. 28 of the GDPR, as part of the study.

The participation in the "THE PARTNER STUDY" Study implies that, in compliance with current legislation, in addition to the Principal Investigator and the staff of Center_____, also the staff of the Promoter or external companies who carry out the monitoring and verification of the Clinical Trial/Study on your behalf (specify), the Ethics Committee and the Health authorities will be able, in the cases provided for by law, to know the identifiable data, also contained in the original clinical documentation, in ways that guarantee the confidentiality of your identity, without prejudice to the fact that the collection, transmission to the Promoter (and to other entities such as the CRO), like any other processing, will take place in a pseudonymized form as reported above.

In fact, the medical and authorized staff of the testing center will replace the name with a code according to a process called "pseudonymization". Only authorized personnel of the Reference Center

possess the decryption key which, if necessary, can be used to reconnect the pseudonymised data to your name, as in the case of a control visit, inspection or audit by the Authorities (e.i Ethics Committees).

At the conclusion of the "THE PARTNER STUDY" study, the data will be disseminated only in a strictly anonymous form, for example through scientific publications, statistics and scientific conferences without the data being able to be traced back to you.

5. Data retention period.

The personal data being processed will be kept by the Padua University Hospital and the Site for a period of 10 years from the conclusion of the study "THE PARTNER STUDY" in compliance with the provisions of the study protocol itself and in any case for the period necessary to fulfill the purpose for which they were collected. At the end of this period, the personal data will be deleted or stored in an anonymized form, in compliance with the principle of limitation of conservation referred to in the art. 5, par. 1, point. e) of the GDPR.

In any case, at the external parties who may collaborate with the Promoter for the management, processing and/or statistical analysis, the data are retained only for the period of time not exceeding that necessary to complete the entrusted activities and subsequently destroyed.

The contact data may be used, during the aforementioned retention period, if you have given specific consent, to inform about any further study and research activities.

6. Transfer of data to the Promoter based in the EU or based outside the EU or to international organisations.

Your data will be transmitted to the Promoter of the Study "THE PARTNER STUDY" which has its registered office in a European Union country. The Promoter may transfer data to affiliates of the corporate group and to third parties operating on its behalf, in countries outside the European Union, but such transfer may only be carried out in compliance with the conditions set out in Chapter V of the GDPR:

- Adequacy decision issued by the European Union;

or

b) Use of Standard Contractual Clauses approved with Implementing Decision (EU) 2021/914 of the European Commission of 4 June 2021.

7. Exercise of your rights.

You may exercise the rights indicated in the articles. 15-22 of EU Regulation 2016/679:

- to access personal data;

- integrate them,

- update them,

- rectify them,

- delete them pursuant to art. 17 of the GDPR and where one of the exceptions referred to in paragraph 3 does not exist;

- right to obtain the limitation of processing (art. 18 of the GDPR);

- the right to object to processing;

- revoke consent at any time if the processing is based on your explicit consent.

In case of revocation of consent, the biological samples related to you will be destroyed without prejudice to any conservation obligations envisaged for samples collected for treatment purposes.

You can exercise the rights listed above by contacting the Site Center directly, even without formalities (email, letter, etc.), in the person delegated to process the data_____
_(Name, surname and email address).

These rights can be exercised by contacting the Data Protection Officer (DPO) at the following e-mail address:_____

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In addition to exercising the rights listed above, you also have the right to lodge a complaint with the competent Data Protection Authority (www.garanteprivacy.it Italy) or _____

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I, the undersigned, Scientific Manager/Collaborator of the Scientific Manager, Dr. _____(name and surname) confirm that I have read to the patient (name and surname)_____ the Information Note on the processing of personal data for the patient indicated above, that I have responded to the questions that he formulated and verified that he understood their content in his full capacity to understand and want.

Last name and Surname (in block letters)_____

Signature _____

Date _____

INFORMED CONSENT FORM TO THE PROCESSING OF PERSONAL DATA

Title of the Study	**THE PARTNER STUDY. AN INTERNATIONAL PROSPECTIVE OBSERVATIONAL STUDY ON PEDIATRIC PATIENTS WITH VERY RARE TUMORS.**
Protocol code	
Center's name	
Principal Investigator's name	
Principal Investigator's contact details	

The patient/data subject_____ born in _____ resident in _____,

I, the undersigned _____

born in_____ on ___/___/_____

as mother/legal guardian/parent 1 of the minor mentioned in the epigraph

I have read and understood the information provided pursuant to Article 13 of EU Regulation 2016/679, which is provided to me together with this document, of which it forms an integral part, and that I have received all the comprehensible and complete information and answers to the questions I have asked, for

which this declaration is issued:

a) □ **agree** □ **disagree**
to the processing of my personal data pertaining to 'THE PARTNER STUDY' within the limits and in the manner indicated in the information supplied to me herewith and to the processing of data, including particular data relating to health

b) □ **agree** □ **disagree**
to know any unexpected information that may emerge during THE PARTNER STUDY (incidental finding).

c) □ **agree** □ **disagree**
to be contacted, during the retention period referred to in Point 5 above, to be informed of any further study and research activities, for which, in case of accession, further consent will have to be requested.

d) □ **agree** □ **disagree**
to the conservation of biological samples for a period of 10 years from the conclusion of THE PARTNER STUDY.

I, the undersigned _____

born in_____ on ___/___/_____

as father/parent 1 of the minor mentioned in the epigraph

I have read and understood the information provided pursuant to Article 13 of EU Regulation 2016/679, which is provided to me together with this document, of which it forms an integral part, and that I have received all the comprehensible and complete information and answers to the questions I have asked, for which this declaration is issued:

a) □ **agree** □ **disagree**
to the processing of your personal data pertaining to 'THE PARTNER STUDY' within the limits and in the manner indicated in the information supplied to me herewith and to the processing of data, including particular data relating to health;

b) □ **agree** □ **disagree**
to know any unexpected information that may emerge during THE PARTNER STUDY (incidental finding);

c) □ **agree** □ **disagree**
to be contacted, during the retention period referred to in Point 5 above, to be informed of any further study and research activities, for which, in case of accession, further consent will have to be requested;

d) □ **agree** □ **disagree**
to the conservation of biological samples for a period of 10 years from the conclusion of THE PARTNER STUDY.

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Name and Surname Mother/Legal guardian/Parent 1 *(in block letter*) _____

Signature _____

Date _____

Name and Surname Father/Parent 1 *(in block letter*) _____

Signature _____

Date _____