



Request form for access to IMMUCan samples and/or data

Applicants are invited to submit additional documentation that may facilitate review (e.g. preliminary data or publications) of their proposal as supplementary appendices.

This form and any accompanying documents must be submitted to: 1828@eortc.org

1. PROPOSAL IDENTIFICATION

PROPOSAL TITLE:

PROPOSAL REQUEST DATE:

REQUESTOR NAME:

INSTITUTION WHERE THE RESEARCH IS CONDUCTED:

NAME AND ORGANIZATION OF IMMUCAN CONSORTIUM PARTNER INVOLVED (if applicable):

WHAT IS THE MAIN SCOPE OF YOUR PROJECT (Meta-analysis, translational research, statistical or methodological research, others):



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CONTACT DETAILS (Scientific Leader):

NAME :	
ADDRESS:	
TEL:	
E-MAIL:	

Does your research make use of or intend to develop a software that falls under EU Medical Device Regulation or Artificially Intelligence Regulation?

<p><i>The newly enforced EU MDR and AI Act applies to processing software intended to provide information for: diagnosis, prevention, monitoring, treatment, or alleviation of a disease. It applies to software that provides a diagnosis or therapy by itself, but also to software that merely provides information intended to inform a medical professional in making the final diagnostic or therapeutic decision.</i></p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes, If yes, please clarify:</p>

Does your research qualify as non-commercial research?



Non-commercial research means that the research proposed is:

- *initiated and conducted by an academic entity or a not-for-profit organization; and*
- *aimed at dissemination of the results to the public/scientific community; and*
- *not intended for commercial purposes, i.e., no exploitation of the outcome, no financial gain to the requestor (nor any involved third party), no exclusive rights granted to a commercial partner, no further use of the insights of the research, development, production, or manufacture for commercial purposes; and*
- *not intended to transfer the intellectual property rights in the results of the research to the funding party, and*
- *the eventual profits are reinvested into research.*

No

Yes, If yes, please specify the purpose of the project



PROJECT DESCRIPTION AND NEEDS

RESEARCH QUESTION(S):

ABSTRACT OF RESEARCH PLAN (including BACKGROUND, OBJECTIVES AND (IF APPLICABLE) EXPERIMENTAL TECHNIQUES TO BE APPLIED ON THE SAMPLES i.e. sequencing, IHC) max. 300 words

ANALYSIS PLAN (including statistical method if applicable):

Does the proposal require the use of biological material from the IMMUcan biobank?

Yes

If yes, please specify the type of samples and insert the estimated quantity and timepoints per patient:



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<input type="checkbox"/> No	samples per patient	tick if required	quantity	Timepoints (registration/progression/surgery*)	thickness
	FFPE blocks	<input type="checkbox"/>	1		na
	FFPE slides	<input type="checkbox"/>			µm
	tumor DNA	<input type="checkbox"/>	ng		na
	tumor RNA	<input type="checkbox"/>	ng		na
	germline DNA	<input type="checkbox"/>	ng		na
	whole blood PAX RNA tube	<input type="checkbox"/>	1		na
	Viable PBMC (aliquots)	<input type="checkbox"/>			na
	Plasma from BCT STRECK cfDNA aliquot	<input type="checkbox"/>	1		na
	Plasma from EDTA (aliquots)	<input type="checkbox"/>	max 3		na
	Serum from SST (aliquots)	<input type="checkbox"/>	max 2		na

***Registration**= for all cohorts

Progression= for the following cohorts only: BC1, NSCLC, RCC, H&N1

Surgery= for the following cohorts only: BC2/3

Does the proposal require the use of the clinical data collected in IMMUCAN ?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, list the variables requested: <ul style="list-style-type: none"> <input type="checkbox"/> Baseline/Patient characteristics <input type="checkbox"/> Samples Characteristics <input type="checkbox"/> Lines of treatment <input type="checkbox"/> Regimens <input type="checkbox"/> Progressions

Does the proposal require the use of molecular/cellular data?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	if yes, specify: <ul style="list-style-type: none"> <input type="checkbox"/> RNA seq <input type="checkbox"/> Whole Exome Sequencing <input type="checkbox"/> multiplex Immunofluorescence <input type="checkbox"/> Imaging Mass Cytometry <input type="checkbox"/> Digitalized H&E slide

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2. PROJECT IMPLEMENTATION DETAILS

TIMELINES: What are the expected timelines of the project?

For the data analysis
For the 1st publication of the results
Expected project completion date

HAVE YOU ALREADY OBTAINED THE ETHICAL COMMITTEE POSITIVE OPINION FOR THIS PROJECT? If yes, please attach all documents that were sent/required to your EC as well the positive opinion document itself. If you consider it is not applicable, please justify below

[Redacted area]

SOURCE OF FUNDINGS:

[Redacted area]

Please note that a financial contribution can be requested.



AUTHORSHIP (for the IMMUCAN representatives)

By default, the IMMUCAN/IMI consortium will need to be acknowledged. No automatic authorship positions are claimed on papers resulting from your research unless IMMUCAN partners are contributing to it. If one or several positions should be attributed to IMMUCAN members, please indicate them below:

PLANNED EXPLOITATION AND OWNERSHIP OF INTELLECTUAL PROPERTY RIGHTS OF RESEARCH RESULTS (if applicable)



3. PRIVACY REQUIREMENTS

As of May 25, 2018, the General Data Protection Regulation (GDPR) has been in force, enhancing and reinforcing privacy protection across the European Union. While the core principles remain consistent with previous legislation, the GDPR introduces several new emphases and requirements to strengthen data protection.

Under EU law, the processing of sensitive data (such as health data) on a large scale mandates the completion of a Data Protection Impact Assessment (DPIA). Given that the data you have requested are governed by EU regulations, you will assume the role of Data Controller for the data used in your Research Project. It is crucial that your Data Protection Officer (DPO) is actively involved in the design and implementation of your research plan. This involvement is essential to ensure compliance with privacy and data protection requirements associated with the processing of personal data in your Research Project.

The primary goal is to achieve a pragmatic balance between minimizing the risk of re-identification and maintaining the utility of the data. To ensure adherence to these standards, please provide the following acknowledgments.

4.1 Description of the third parties involved in your research (agreements and roles)

- We confirm that the appropriate agreement(s) (e.g., Data Processing Agreements) including GDPR requirements with other involved parties (if any, such as service providers, cloud providers) have been put in place indicating the role and responsibilities, and accountability of each party.

Please, provide any additional information or specific details that may be relevant:

4.2 Description of the Data Transfers outside EU

- We intend to share or to transfer data outside EU, to conduct the research. And, prior such data sharing, we are taking the necessary steps to assess the legal framework for the third countries where the data are going to be transferred (i.e., a data transfer impact assessment is conducted).
- (If the data requestor is located outside EU) We are willing to sign Standard Contractual Clauses (SCCs) to ensure compliance with data protection requirements for transferring data outside the EU.
- We do not intend to share or to transfer data outside EU.

Please, provide any additional information or specific details that may be relevant:



4.3 Description of context related Transparency

- We are committed to providing patients with the necessary level of information on how their personal data is protected in an accessible and understandable format, in accordance with our responsibilities as Data Controller. To ensure transparency, we utilize specific channels to communicate this information effectively. These channels include Separate Privacy Notices that explain our role as Data Controller, the purposes for which their data will be used, and the measures we have in place to protect their personal information; Website References where patients can find comprehensive information about our data protection practices in our privacy policy available on our website. This policy clarifies our role as Data Controller for our research projects and outlines the purposes for which the acquired data will be used.

Please, provide any additional information or specific details that may be relevant:

4.4 Description of measures taken to ensure Purpose Limitation

- We will ensure that internal use of the requested data is not used outside the research purpose for which the data is initially requested.

Please, provide any additional information or specific details that may be relevant:



4.5 Description of measures taken to ensure Data Minimization

- We will ensure that only the data relevant to the purpose described above is requested. We confirm that no unnecessary data will be requested, strictly adhering to the principle of data minimization to achieve the stated objective.

Please, provide any additional information or specific details that may be relevant:

4.6 Description of Data Protection Impact Assessment (DPIA)

- We confirm that a Data Protection Impact Assessment (DPIA) has been/will be completed, as we will be accessing special categories of personal data, such as health conditions (e.g., cancer data) or genetic data. These types of data can pose a 'high risk' to individuals, including the potential loss of control over personal data, exposure of identity, or unauthorized reversal of pseudonymization.
- We confirm that the initiation of the DPIA follows our internal risk management and compliance procedures. The processing will only proceed if the DPIA concludes that appropriate safeguards are in place and the residual risk is deemed acceptable in line with applicable data protection standards.

For more information, please refer to the Data Protection Impact Assessment (DPIA) webpage of the European Union.

Please, provide any additional information or specific details that may be relevant:

4.7 Description of measures taken to ensure data security

- We have put in place the necessary technical and organizational measures to protect the requested data (such as but not limited to due diligence and due security measures to protect information in coherent and effective manner by aligning or adhering to framework such as ISO27001, NIST 800 series etc, or controlled access to health and genetic data, mechanisms to prevent unauthorized disclosure, privacy exhibit up to date, etc).

Please, provide any additional information or specific details that may be relevant:

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Terms of Use for using IMMUCan data and/or biological material in non-EORTC research

Acceptance of Terms of Use

1. European Organisation for Research and Treatment of Cancer (EORTC) is the legal sponsor, custodian and data controller of the data and/or biological material generated by IMMUCan partners within the IMI2 project entitled “Integrated iMMUnoprofiling of large adaptive CANcer patient cohorts” (IMMUCan).
2. By accessing and using the data and/or biological material provided by **EORTC** in the scope of your specific project, you shall be deemed to have accepted to be legally bound by these terms (hereinafter referred to as “**Terms of Use**”). If you do not agree to these Terms of Use, you are not entitled to receive and use the IMMUCan data and/or biological material.
3. In addition, EORTC may require that you comply with additional terms beyond these Terms of Use (if any), which will be notified to you in writing at the time of the approval of your request or which may require a formal agreement to be put in place with you/your institution (for example in the case of sharing data with non-EU entities, etc.).

Administrative Fee

4. EORTC will charge an administrative fee for managing and processing approved requests. The fees* are available on the IMMUCan website [IMMUCan - European immuno-oncology profiling platform](#). Any other relevant costs will be estimated in advance and charged to the requestor: e.g. costs for sample logistics, costs for accessing data from external databases (e.g. genetic data), etc.
For commercial requests, specific fees will apply and will be calculated on a case-by-case basis.

**These amounts represent the administrative fees as of 2026. EORTC reserves the right to adjust the amounts indicated in this clause 4 on a yearly basis for inflation purposes. Any such adjustments shall be communicated to you in writing prior to receiving the EORTC data.*

5. For the above purpose, EORTC shall address an invoice to you/your institution. EORTC will collect from you the required financial information at the time of request approval. Payments are due, at the latest, within thirty (30) days from the date of invoice, it being understood that the requested data and/or biological material will only be shared after the payment has been received. The fees paid under these Terms of Use are non-refundable.

Conditions of Use

6. Subject to these Terms of Use, EORTC grants you/your institution a royalty-free, non-exclusive, non-transferable, non-assignable license to use the data and/or biological material solely for the following purposes:

- a. use specifically for the project for which you requested the data and/or biological material in the request form (hereinafter the “**Project**”);
 - b. modification or adaptation of the dataset(s) to suit the needs of the Project;
 - c. publication of the results arising out of the Project.
7. Subject to these Terms of Use, and without prior written authorization by EORTC, you are explicitly prohibited to:
- a. further copy, distribute or sell the data and/or biological material to any third party that was not declared to and accepted by EORTC at the time of the request;
 - b. post the provided data on a public data repository/website, unless in a form of results and/or otherwise agglomerated data;
 - c. further commercialize any applications or any other material that you might develop using the data and/or biological material without prior written agreement from EORTC;
 - d. attempt to identify data subjects or any action which is likely to lead to subject identification;
 - e. publish any individual patient data (except when fully anonymized or agglomerated) or any other type of data that puts data subjects under the risk of potential intentional or unintentional identification, unless specifically and explicitly authorized by the data subject;
 - f. use the data and/or biological material for other purposes than the Project;
 - g. use the data and/or biological material for unlawful purposes or present results in a misleading way. Such instances include, but are not limited to:
 - presenting the data in a misleading or incorrect manner, or misrepresenting the data; or
 - using the data and/or biological material to promote or support any illegal activities.

In the case of Biological Material use, specifically these additional terms (h. to m.) also apply:

- h. You shall bear the logistic costs of the biological material from IMMUCAN’s biobank (Luxembourg Institute of Health, with offices at 1A-B Rue Thomas Edison, L-1445, Strassen, Luxembourg; hereinafter “LIH”) to your institution. For this purpose, EORTC will provide you with a quote from LIH for your approval. An invoice will be addressed to you/your Institution directly. EORTC shall bear no cost or liability for this shipment, or any issue related to it. The biological material shall be maintained with requisite care, skill and diligence, in accordance with the requirements laid down by all applicable laws, regulations and guidelines.
- i. You/your Institution will check the quality of the biological material upon arrival and will contact EORTC immediately for further clarification if the quality check reveals deficiencies of such a degree that the biological material received would not be suitable for the purpose of the Project.
- j. The biological material shall be maintained at Institution’s premises under the responsibility of you/your Institution. The biological material shall not be sold or destroyed or further distributed or used without prior written consent of EORTC.
- k. You shall only use the strict amount of biological material for the Project and shall not use the biological material for any other purposes. Any remaining biological material shall be shipped back to LIH at you/your Institution cost, or destroyed

upon instruction from EORTC. In the latter case, a certificate of destruction shall be provided upon request by EORTC.

- I. EORTC has no obligation to transfer to you/your Institution any documents and/or biological material other than what is strictly needed by Institution for the performance of the Project.
8. You must:
- a. ensure that the Project has received, when applicable, an appropriate ethical approval and / or any other approval(s), and that it is otherwise legitimately performed in compliance with all applicable legislation, including but not limited to any local or national rules applicable to re-use of patient data from in a given country or territory;
 - b. ensure that any third party involved in the Project complies with these Terms of Use, as applicable;
 - c. process the data and/or biological material in a way that will make any inappropriate access to the data and/or biological material or any breach to data privacy highly unlikely, by (among other measures) using appropriate technical tools;
 - d. limit all processing of the data and/or biological material to entities based within the European Union or inform EORTC about any need to transfer data and/or biological material to any party based outside the European Union prior to any transfer or any agreement to transfer as additional constraints may apply;
 - e. publish the results arising out of the Project, which shall be done by these Terms of Use and applicable international standards, including but not limited to the recommendations from the International Committee of Medical Journal Editors (ICMJE);
 - f. submit any intended publication or any other public disclosure of results to EORTC and / or EORTC's designee for its revision at least thirty (30) days in advance (or as otherwise instructed by EORTC), prior to public disclosure;
 - g. clearly state in all your communication: "*The authors thank the European Organization for Research and Treatment of Cancer and the IMMUCan consortium (project funded under the IMI 2 Joint Undertaking under grant agreement No 821558 by the European Union's Horizon 2020 research and innovation programme and EFPIA.) for permission to use the data for this research*" and "*The contents of this publication and methods used are solely the responsibility of the authors and do not necessarily represent the official views of the EORTC. Neither the IMMUCan partners, nor IMI, EU and the EFPIA are responsible.*";
 - h. only store the data as long as necessary for the purpose of this Project and do not store it any longer than the archiving time legally required by the legislation applicable to your activities and/or to the Project. A certificate of destruction or anonymization shall be provided upon request of EORTC;
 - i. provide the information on, modify, correct or destroy the data and/or biological material or parts thereof upon specific request of EORTC at any moment, in particular in relation to data subject rights and requests; such actions shall not generate any costs or liability for EORTC and for IMMUCan partners;

- j. immediately inform EORTC about any breach to data privacy in relation to data you received from EORTC or any breach of these Terms of Use (to dpo@eortc.org);
- k. send EORTC the reference of any resulting scientific publication within 2 months of the publication.

Data Protection

9. In relation to the processing of the data requested by you and provided by EORTC under these Terms of Use, you become an Independent Data Controller on your own, exclusively for this particular re-use of the data. By agreeing with these Terms of Use you confirm to ensure that any personal data processing activities are compliant with the applicable laws, including but not limited to the General Data Protection Regulation 2016/679 (“**GDPR**”), and are able to demonstrate such compliance:
 - a. you ensure that you determine and document the legal basis and the lawfulness of personal data processing activities performed in the scope of your Project.
 - b. you process the personal data only for your Project purposes defined in these Terms and only to the minimum extent necessary. For any re-use of personal data for new purposes, you shall perform and document the compatibility assessment required by GDPR Art. 6(4);
 - c. you take reasonable steps to ensure the personal data are accurate and kept up to date;
 - d. you confirm you will process the shared personal data lawfully, fairly and in transparent manner. You will provide the information required by GDPR Art.14 to data subjects in a clear and accessible form, or, where you rely on a valid exemption, you must implement appropriate alternative transparency measures (e.g., publish a privacy notice online) and document your assessment;
 - e. you will process personal data in a way that ensures appropriately security of personal data and maintains their integrity and confidentiality;
 - f. you restrict access to the personal data, so it is limited to those personnel and contractors who are subject to confidentiality obligations;
 - g. you are responsible to ensure that any systems and environments used to host or process the requested data comply with the data protection and security requirements;
 - h. you may delegate partially or entirely any of the processing activities to vendors and sub-contractors and in doing so, you shall enter into a written agreement with the processor, as required by the Article 28 of GDPR. You remain fully responsible for your processors. Where processors engage sub-processors, you shall ensure equivalent obligations and appropriate approvals.
 - i. You define and apply a retention period proportionate to your Project and securely delete or anonymise the personal data upon expiration or upon termination of these Terms of Use, unless longer retention is required by law and documented.
 - j. You maintain records of processing activities and are able to demonstrate compliance with applicable data protection laws such as the GDPR;
 - k. You will conduct a DPIA where your Project is likely to result in high risk to the data subjects, and if necessary, consult the supervisory authority prior to the Project;

- l. You shall not transfer the personal data outside the EEA or to an international organization without a valid transfer mechanism;
 - m. you acknowledge that if the data being used for this research includes genetic data, you shall comply with additional safeguards in connection with the processing of genetic data following GDPR and related applicable national laws. You will implement all necessary administrative, physical, and technical safeguards designed that take into consideration the nature of such data and the privacy and legal risks consequently involved. The additional security measures shall include but not be limited to ensuring a proper controlled access to the data, implementing access management procedures, keeping a record of access to the data, establishing restrictions for cross-border data transfers or any other necessary security measures. You understand that you have a duty to stay informed of possible changes to such laws during the term of this research.
10. Although you are responsible to assess and comply with the formalities requested by GDPR for the data breaches and complains that occurs at your side and in relation to the data provided by EORTC, EORTC, as the original controller, would like to be informed (dpo@eortc.org) within the shortest delay possible about any risk or high risk data breaches, as this might have impact on EORTC's reputation or image.
11. In the event of a data subject request, and since you are not in direct contact with the sites from where the patient data shared with you were initially collected nor in the position to identify the data subject, EORTC will provide reasonable assistance so that you complete the data subject request within the timelines and formalities requested by GDPR.
12. For the sake of clarity, these Terms of Use are applicable only when the requestor of the data is a person/entity within the European Union entity. When the requestor is a non-EU person/entity, the Terms of Use might not be sufficient and EORTC might need to put in place additional contractual clauses to cover this.

Disclaimers

13. The data and/or biological material is provided on an "as is" basis without warranties of any kind. EORTC and IMMUCAN partners do not make any representations or warranties whatsoever and, to the fullest extent permitted by the law, hereby disclaim warranties, whether express, implied or statutory, to you or any third party in relation to the use of the data and/or biological material, including but not limited to any warranty as to the accuracy, correctness, reliability, timeliness, non-infringement, title, quality or fitness for any particular purpose of the data and/or biological material.
14. To the fullest extent permitted by law, EORTC and IMMUCAN partners shall not be liable to you or any third party for damage or loss of any kind, including but not limited to direct, indirect, punitive, special or consequential damages, loss of goodwill, loss of business resources, income, revenue or profits, lost or damaged data, or damage to your computer or other property, arising directly or indirectly from your or any third party's use of, or inability to use, the data and/or biological material or the results of the Project.

Indemnity

15. You agree to fully indemnify EORTC and IMMUCan partners, and to hold EORTC and IMMUCan partners harmless from any and all claims, demands, losses, liabilities, costs and expenses (including but not limited to legal costs) against EORTC and IMMUCan partners arising directly or indirectly from (i) your use of the data and/or biological material; (ii) your breach of any of these Terms of Use; (iii) your violation of any third party rights; or (iv) any claims made by a third party in connection with the third party's use of the data/biological material/results or any derived analyses or applications which you have generated.

Ownership and Intellectual Property

16. You acknowledge that you understand and agree that:
- a. You are not the owner of the data and/or biological material, and their ownership is not anyhow affected by these Terms of Use;
 - b. without prejudice to clause 6.c above, and except for intellectual property rights that may be claimed by a third party that participated in the studies where the data and/or biological material was originally collected and / or generated, you retain the intellectual property rights exclusively and specifically on the results generated in your Project. For the sake of clarity, any intellectual property rights otherwise related to the provided data are not affected by these Terms of Use and remain with EORTC and IMMUCan partners.

Breach of the Terms of Use

17. Without prejudice to any other rights that EORTC may decide to exercise, the breach of these Terms of Use shall result in the cancellation of the license to use the data and/or biological material granted to you under clause 5. These Terms of Use (except for clause 5) shall survive the cancellation of the license granted herein.

Governing Law

18. These Terms of Use shall be governed by and construed in accordance with Belgian laws. You irrevocably agree that Belgian courts shall have exclusive jurisdiction in relation to any dispute arising from or relating to these Terms of Use.