IMMUcan POLICY ON BENEFICIARY AND THIRD PARTY ACCESS TO PROJECT DATA AND HUMAN SAMPLES

(Version 7th Feb. 2020)

Explanatory note

1. Foreword

This explanatory note serves to explain and supplement the rights and obligations of parties contributing samples and data to the IMMUcan project (immucan.eu), either as a Beneficiary (i.e. member of the IMMUcan consortium) or a Third Party (i.e. any entity not a member of the IMMUcan consortium). This document is part of the IMMUcan Policy on Beneficiary and Third Party Access to the Results and Model for Access to Human Samples, together with the document attached as Appendix 1 to this explanatory note. In case of any inconsistency or contradiction between this explanatory note with the document attached as Appendix 1, the provisions of the document attached as Appendix 1 shall prevail. In any event, the provisions of the Consortium Agreement shall prevail in case of any inconsistency or contradiction with the provisions of this document.

2. Principles

	Beneficiaries	**Third Parties**
Ethical approval	Beneficiaries and Third Parties are solely responsible for obtaining applicable ethical approval covering their use of IMMUcan data and human biological material for other purposes than the completion of IMMUcan.	
Compliance with laws.	Beneficiaries and Third Parties will comply with all legal and regulatory requirements (including but not limited to the EU GDPR requirements). To the extent legally required, Beneficiaries and Third Parties will inform EORTC about the purpose of any use of IMMUcan data for other purposes than the completion of IMMUcan.	
Access to IMMUcan data.	Beneficiaries have access to IMMUcan data as soon as i) data are available for the implementation of the Project but also for further research activities during and after the Project and ii) they provide evidence to be a reliable partner from data protection perspective. Any commercial use of IMMUcan data will have to be negotiated with the Beneficiaries owning the data concerned.	- *Access of contributing Third Parties to patient measurement data generated on the human biological material they have contributed.* Third Parties providing human biological material (SPECTA clinical sites and clinical trial sponsors) have access for further research to the measurement data generated on the human biological material from their patients only, provided that a separate agreement has been put in place by the Coordinator of IMMUcan. Any commercial use will have to be negotiated with the Beneficiaries owning the data. - *Access of Third Parties to IMMUcan data not from*

		human biological material contributed by the Third Party. The IMMUcan consortium may under a separate agreement (between the Beneficiary owning the relevant data and the Third Party) grant access to Third Parties to IMMUcan data (beyond the possible access for Third Parties to the measurement data generated on the human biological material they have contributed) for further research. Such access is subject to a decision by the Beneficiaries owning the data and the IMMUcan consortium. For the avoidance of any doubt, granting of such access during the Project is up to the discretion of the Beneficiaries owning the data. Any commercial use will have to be negotiated with the Beneficiaries owning the data.
Access to human biological material.	Third Parties and Beneficiaries can request access to human biological material for further research during and after the Project. Such access will need prior approval taking into account consortium priorities, contributions to the Project, and the scientific quality of the request.	
Cost allocation for use outside of IMMUcan	Beneficiaries/Third Parties shall bear all (data extraction, sample transport and analysis) costs caused by their use of IMMUcan data and human biological material, other than for the completion of IMMUcan.	
Access to data generated by further research on the human biological material collected under IMMUcan	Beneficiaries/ Third Parties own the data generated from the further research of the human biological material. However, such data will be shared with all Beneficiaries and will be included in the IMMUcan database. Access to such data is granted to Beneficiaries for further research activities, during and after the Project. Third Party access is subject to prior approval of the Beneficiary/ Third Party owning the data concerned.	
Access to output generated by further research with IMMUcan data	Beneficiaries/ Third Parties own the output generated by their further research with the data from the IMMUcan database. Beneficiaries and/or Third Parties do not have the obligation to share this output with other Beneficiaries or to include it in the IMMUcan database.	
Publication of data	Beneficiaries and/ or Third Parties must obtain consortium approval for any publication involving data generated by IMMUcan. Consortium approval is not mandatory for	

	publications involving only data resulting from the research of human biological material outside of IMMUcan.
Public repository	The IMMUcan data will be posted on a public repository towards Project end with regulated access.

All requests for access to human biological material and/ or data shall be made following the procedure below:

3. Procedure for requesting access during the Project

3.1. Access to human biological material for further research

a. Third Parties and/or Beneficiaries which are interested in accessing human biological material for further research will submit a request for access to the Project Coordination Team (PCT) by email (pct@immucan.eu). Requestor should include in the email all the information listed in the template request for access.

b. The PCT will prioritize the requests in accordance with the priority tiers set forth in Appendix 1.

c. The PCT will forward the information and recommend a decision ("positive" or "positive provided adjustment to the proposal" or "negative") to the Executive Board. The Executive Board shall confirm whether it agrees with the PCT's proposal during its monthly meeting.

   i. In case of a negative decision by the Executive Board, the PCT will feedback the decision to requestor.

   ii. In case of a positive or "positive provided adjustment to the proposal" decision, the PCT will forward the Executive Board decision to the Beneficiaries that own the requested human biological material.

d. The Beneficiaries owning the requested human biological material shall, within 30 days, confirm their agreement with the decision taken by the Executive Board, or provide their reasoned objections to such decision.

e. The PCT will feedback the decision to requestor.

f. For the sake of transparency, PCT will keep up to date a list of requested access and decisions including short justifications that is posted on the project internal SharePoint.

3.2. Access to IMMUcan data for further research

a. Beneficiaries shall have unrestricted access to all IMMUcan data included in the IMMUcan database for further research. Beneficiaries shall send an email to EORTC (dpo@eortc.org) informing about the main purpose of their further research to the extent required to comply with GDPR obligations.

b. Third Parties that have contributed with patient material and are interested in accessing IMMUcan data for further research may submit a request for access in the template request for access form attached below to the PCT by email (pct@immucan.eu).

   i) The PCT will forward the information and recommend a decision ("positive" or "positive provided adjustment to the proposal" or "negative") to the Executive

Board. The Executive Board shall confirm whether it agrees with the PCT's proposal during its monthly meeting.

a) In case of negative decision by the Executive Board, the PCT will feedback the decision to requestor.

b) In case of positive or "positive provided adjustment to the proposal" decision, the PCT will forward the Executive Board decision to the Beneficiaries that own the data.

ii) The Beneficiaries owning the requested data shall take a decision on the request for access within 30 days after the decision made by the Executive Board. The PCT will feedback the decision to the Third Party requestor, after which the relevant Beneficiaries may negotiate any additional terms for such access with the Third Party concerned.

iii) For the sake of transparency, the PCT will keep up to date a list of requested access and decisions including short justifications that is posted on the project internal SharePoint.

Template of request for access

1. Request title:
2. Date of request:
3. Person in charge of the request (contact details):
4. Other persons involved in the request (contact details, roles and responsibilities):
5. Only if 3rd party requestor: IMMUcan consortium members already contacted and aware about the request: names, organisations.
6. What is the main scope of your research:
7. Summary of the research [word limit 100 words, can be shorter]
8. Background/rationale of the proposal [word limit 100 words]
9. Objectives of the proposal: [100 words]
10. Describe the methodology that will be used including endpoints and methods:
11. Describe the type of IMMUcan data and variables of interest you want to access (clinical, molecular, time points, type of patients, etc.):
12. Describe the type of IMMUcan HBM you want to access (types, quantity…):
13. Have you already obtained the ethical committee approval for this project? If not, please explain how it is planned.
14. Indicate expected timelines of the project. Data analysis, First publication of results, Expected completion date.
15. Financing. If applicable, specify any financial resources that are available to cover the project costs.
16. Indicate the number and journal of the publications that you anticipate and for each of them, the subject of the publication.
17. Authorship, please indicate the authorship position(s) attributed to IMMUcan representative(s).
18. Planned exploitation and ownership of intellectual property rights of research results (if applicable).

APPENDIX 1

IMMUCAN POLICY ON BENEFICIARY AND THIRD PARTY ACCESS TO THE RESULTS AND MODEL FOR ACCESS TO HUMAN SAMPLES

INTRODUCTORY STATEMENT

(A) IMMUcan will collect Human Samples and data from Beneficiaries and Third Parties and will analyse these Human Samples and data to generate data (the "**Project Measurement Data**") which will be included in a central database (the "**IMMUcan Database**").

(B) The Access Rights to Project Measurement Data (constituting Results of the Project) are set out in the Consortium Agreement.

(C) In order to incentivize Third Parties to contribute Human Samples to IMMUcan, such contributing Third Parties shall have the possibility to receive Access Rights to the Project Measurement Data during the Project.

(D) Furthermore, it is expected that not all collected Human Samples will be used in the generation of the Project Measurement Data within the Project. It is the intention to grant access to both Beneficiaries and Third Parties to the unused Human Samples for other use than the Allocated Work as set out in Annex 1 to the Grant Agreement, meaning for further research activities. The measurement data arising out of the Research Use of such Human Samples (**"Additional Measurement Data**") must be included in the IMMUcan Database as well.

(E) In accordance with Annex 1 to the Grant Agreement, the Consortium will develop a policy for the access of Third Parties to Project Measurement Data (Deliverable 3.5: the "**Policy on Beneficiary and Third Party Access to the Results**") and a model governing the access to Human Samples (Deliverable 1.5: the "**Human Samples Access Model**"). This document further sets out the principles guiding the Policy on Beneficiary and Third Party Access to the Results and the Human Samples Access Model (the "**Policy**").

1. GENERAL

1.1. Capitalized terms used in this Policy shall bear the same meaning as defined in the Consortium Agreement, or, where applicable, the Grant Agreement, unless otherwise specifically defined herein.

1.2. Nothing in this Policy is meant to amend, replace or otherwise alter any of the provision of the Consortium Agreement. In case of conflict or inconsistency between the terms and conditions of this Policy and of the Consortium Agreement, the terms and conditions of the Consortium Agreement shall prevail to the extent of the conflict or inconsistency.

1.3. For the avoidance of doubt, any access or usage right set forth herein shall be subject to full compliance with the applicable Data Protection Legislation and Clinical Practice Legislation.

2. ACCESS TO DATA

2.1. The IMMUcan database will include the following categories of data:

2.1.1. Project Measurement Data. Such Project Measurement Data are:

(a) owned by the generating Beneficiary in accordance with the provisions of the Consortium Agreement; and

(b) subject to the Access Rights in accordance with the provisions of the Consortium Agreement:

(i) Beneficiaries have Access Rights for implementation of the Project, and for Research Use during and after the Project.

(ii) In principle, Third Parties only have Access Rights for Research Use after the Project; however, in accordance with Clause 8.4.1 of the Consortium Agreement, Third Parties contributing Human Samples shall have, subject to a reasoned written request, Access Rights for Research Use to the Project Measurement Data relating to the Human Samples they have contributed. In addition, Third Parties shall have the possibility to request early Access Rights to other Project Measurement Data if reasonably required for their further research. Such early Access Rights to other Project Measurement Data need to be approved by the owner of the respective Project Measurement Data and the Executive Board, who shall not be obliged to grant such request.

2.1.2. Additional Measurement Data generated by a Beneficiary. Such "**Beneficiary Additional Measurement Data**":

(a) are owned by the Beneficiary generating such data;

(b) are not Results of the Project; and

(c) will be included in the IMMUcan Database; access to Beneficiary Additional Measurement Data shall be construed in accordance with the Access Rights to Results as set out in the Consortium Agreement.

2.1.3. Additional Measurement Data generated by a Third Party. Such "**Third Party Additional Measurement Data**":

(a) are owned by the Third Party generating such data;

(b) are not Results of the Project; and

(c) will be included in the IMMUcan Database; access to Third Party Additional Measurement Data shall be construed in accordance with the Access Rights to Results as set out in the Consortium Agreement.

This means that:

(i) during and after the Project, Beneficiaries shall automatically have Access Rights for Research Use to such Third Party Additional Measurement Data, on Royalty-Free Conditions;

(ii) during the Project, the Third Parties that have contributed the Human Samples on which the Third Party Additional Measurement Data have been generated, shall, subject to an agreement negotiated by the Project Coordination Team, enjoy Access Rights for Research Use to such Third Party Additional Measurement Data. Any agreement on the transfer of Human Samples provided by a Third Party to another Third Party shall contain provisions adequately safeguarding these early Access Rights for Third Party contributors as well as Access Rights for Beneficiaries;

(iii) other Third Parties have the right to request and receive Access Rights to such Third Party Additional Measurement Data for Research Use on appropriate conditions, to be agreed upon with the Third Party generator.

2.2. For the avoidance of doubt, the other Beneficiaries nor the other Third Parties shall have any Access Rights to the data resulting out of the Research Use performed on Project Measurement Data and/or Additional Measurement Data.

3. DISSEMINATION

3.1. The Beneficiary owning the Project Measurement Data shall have the right to publish its data, in accordance with the Dissemination procedure set out in the Consortium Agreement.

3.2. The Third Party contributing Human Samples shall only have the right to publish the Project Measurement Data relating to the Human Samples it has contributed, subject to the approval of the Beneficiary owning such Project Measurement Data (which shall be bound by the Dissemination procedure set out in the Consortium Agreement). Any such publication shall appropriately acknowledge the contribution of IMMUcan.

3.3. The Beneficiary/Third Party owning the Additional Measurement Data shall have the right to publish such data.

3.4. In the event any Dissemination includes both Project Measurement Data as well as Additional Measurement Data, any such Dissemination must comply with the Dissemination procedure set out in the Consortium Agreement.

3.5. In the event Dissemination includes both Project Measurement Data owned by a Beneficiary as well as Additional Measurement Data owned by a Third Party, any such Dissemination shall be jointly, and must comply with the Dissemination procedure set out in the Consortium Agreement.

3.6. Within the framework of the Dissemination procedure set out in the Consortium Agreement, the Beneficiaries will appoint a representative to an editorial committee receiving all notices made thereunder, and which shall, if required, object to a proposed publication of a Beneficiary or, in the case of point 3.2 above, a Third Party, in accordance with such Dissemination procedure.

4. HUMAN SAMPLES ACCESS MODEL

4.1. Both Beneficiaries and Third Parties will have possible access to the Human Samples for Research Use, during as well as after the Project.

4.2. The transfer of Human Samples to a Beneficiary or a Third Party shall require a separate material transfer agreement, further defining the envisaged use of the Human Samples and the conditions imposed thereon.

4.2.1. Access to Human Samples for implementation of the Project falls within the IMMUcan budget.

4.2.2. Access to Human Samples other than for implementation of the Project, shall be subject to specific conditions, including but not limited to the following:

(a) The Additional Measurement Data will be shared with the IMMUcan Beneficiaries, and will be included in the IMMUcan Database.

(b) The Beneficiary/Third Party shall bear all (transport and analysis) costs for their Research Use of the Human Samples

(c) The Beneficiary/Third Party shall be solely responsible for obtaining the required applicable legal consents and authorizations (including ethics' committee approval) for their envisaged Research Use and for their use of the Human Samples, and any personal data associated therewith.

4.3. The Beneficiary or Third Party concerned shall submit a written request to the Project Coordination Team to access the Human Samples. The Project Coordination Team shall establish which request should be granted, and will give priority to requests which are more likely to generate data which is of interest to IMMUcan, in accordance with the following priority tiers (from highest to lowest priority):

1) Beneficiaries if needed or useful for the implementation of the Action;

2) Beneficiaries and Third Parties if the intended Research Use on the Human Samples is expected to generate Additional Measurement Data that are of the most benefit to the Action Objectives;

3) Beneficiaries and Third Parties if the intended Research Use is expected to generate Additional Measurement Data that is of the most benefit to other Beneficiaries;

4) Beneficiaries and Third Parties if the intended Research Use is expected to generate Additional Measurement Data that are of the most benefit to the wider scientific community;

5) Beneficiaries if the intended Research Use is expected to generate Additional Measurement Data that are of the most benefit to themselves.

6) Third Parties if the intended Research Use is expected to generate Additional Measurement Data that are of the most benefit to themselves.

4.4. In establishing the priority tier of the request, the Project Coordination Team shall take into account that:

(i) a harmonized, comprehensive analysis of a large number of Human Samples takes preference over multiple/ separate analyses on smaller numbers of Human Samples;

(ii) analyses performed in accordance with validated analysis methods are preferred over analyses performed with non-validated analysis methods;

(iii) analyses of which the Additional Measurement Data can be included in the IMMUcan database are preferred over other analyses;

(iv) analyses on peripheral Human Samples (such as stool samples, blood samples, etc.) are preferred;

(v) in the event the intended Research Use envisaged by a Beneficiary and a Third Party is of a similar nature (and hence also fall within the same priority tier), the Beneficiary shall have priority over the Third Party.

4.5. Notwithstanding points 4.3 and 4.4 above, in the event a Beneficiary/Third Party which has contributed Human Samples to the Project, requests access to such Human Samples for Research Use, such Beneficiary/Third Party shall have priority to other Beneficiaries/Third Parties, to the extent such Human Samples are not needed to implement the Project.

4.6. The Executive Board shall take the final decision on the granting of access to the Human Samples, in accordance with the decision-making procedure included in the Consortium Agreement. The approval of the custodian of the Human Samples concerned shall be required.

4.7. Neither Beneficiaries nor Third Parties are allowed to share Project Measurement Data and Human Samples they receive through sharing with further Third Parties, unless required for the implementation of the Project.

5. COMPLIANCE WITH GDPR

5.1. Personal Data

Data identified by IMMUCAN ID, including, clinical data, biological samples, identifiers and metadata accompanying Human Samples and Additional Measurement Data shall be considered as personal data in the view of GDPR and thus GDPR applies fully to the processing activities under the IMMUcan Project.

The Beneficiaries and Third Parties shall not try to re-identify the Data Subjects.

5.2. Controllership

EORTC is the Sponsor of the SPECTA Project and the Coordinator of IMMUcan and thus is the Controller for the processing activities under IMMUcan.

The Beneficiaries and Third Parties shall act as independent data controller for the purpose of processing of that personal data in the scope of their envisaged Research Use.

5.3. Data Subjects Rights

Shall any request from a Data Subject be received in the scope of IMMUcan, the Beneficiaries and Third Parties shall provide reasonable assistance in order to satisfy the Data Subject's request within the timelines defined by GDPR. In their role of independent data controller, the Beneficiaries and Third Parties shall assess and report eventual breaches and address Data Subject's complaints in compliance with applicable legislation. The Beneficiaries and Third Parties shall inform the IMMUcan Consortium about any eventual risk and/or high-risk data breach and Data Subject's complaints as it may affect its reputation.

5.4. Data Protection Impact Assessment

Independently from the legislation applicable to the Beneficiaries and/ or Third Parties, they will perform a Data Protection Impact Assessment prior to the start of the processing activity and implement adequate safeguards in order to ensure residual risks are not high.

5.5. Transfers mechanisms

Any transfer of personal data from controller to controller shall be documented in a written agreement.

Transfer of Personal Data to Beneficiaries is sufficiently documented in the Consortium agreement for Beneficiaries having their main establishment in the EU or in countries with an effective adequacy decision.

Beneficiaries with the main establishment in countries outside EU and without adequacy decision shall be assessed in terms of transfer instruments (mechanisms) by the Coordinator of IMMUcan prior to the transfer. Third Parties shall sign an appropriate Data Transfer Agreement prior to any transfer (access is considered as transfer under GDPR).

6. GENERAL OVERVIEW OF ACCESS RIGHTS FOR FURTHER RESEARCH USE

Access Rights for Research Use	Beneficiaries	Third Parties contributing Human Samples	Other Third Parties	Dissemination
Project Measurement Data	During and after the Project, free of charge	During and after the Project, only to the measurement data generated on the Human Samples they have contributed, and subject to conclusion of template agreement.	After the Project, subject to appropriate conditions to be negotiated with the owner of the data.	- Beneficiary owning the Project Measurement Data; - Third Party contributor, subject to Beneficiaries' approval (owner + Dissemination procedure)

Beneficiary Additional Measurement Data	during and after the Project, free of charge	During and after the Project, only to the measurement data generated on the Human Samples they have contributed, and subject to conclusion of template agreement.	After the Project, subject to appropriate conditions to be negotiated with the owner of the data.	- Beneficiary owning the Additional Measurement Data ; - Third Party contributor, subject to owning Beneficiary's approval
Third Party Additional Measurement Data	during and after the Project, free of charge	During and after the Project, only to the measurement data generated on the Human Samples they have contributed, and subject to conclusion of template agreement.	After the Project, subject to appropriate conditions to be negotiated with the owner of the data.	- Third Party contributor (acknowledging IMMUcan)
Human Samples	During and after the Project, after approval of EB and custodian, subject to the conclusion of an MTA	During and after the Project, after approval of EB and custodian, subject to the conclusion of an MTA	During and after the Project, after approval of EB and custodian, subject to the conclusion of an MTA	N/A