**Explanatory notes INCbase Data Registry and Biomaterial Policy**

**This document governs:**

The legal and organizational aspects of a collectively managed data collection with a centralised infrastructure

- in which health data of a given patient group are collected and entered into the registry’s database by the Participating Members

- in which these data are used for the purpose of scientific research

- and which may include a catalogue of samples (from that patient group) that are kept in a biobank of the Participating Member, which samples may also be used for scientific research.

**Described is:**

- What the data collection consists of

- The role of the Participating Members

- The management structure

- The way in which privacy is safeguarded.

- Under what conditions the data/samples will be made available for research

**Further explanation of some Appendices:**

- The Partners are joint controllers with respect to the Registry. This is legally regulated in Exhibit A part 2 (Joint Controller Responsibility Matrix).

- One of the Partners (the Coordinating Member) manages the database. In this role, this Partner is a data processor. To regulate this legally, Exhibit A part 1 has been added (Responsibilities of the Data Processor). The processor enters into sub-processor agreements with engaged sub-processors.

The Coordinating Member has different roles:

* the role of processor, that hosts and manages the database on behalf of the Participating Members, and
* the role of coordinator, having administrative and coordinating tasks as mentioned in the governance section
* the role of Participating Member.

- Accession to the Registry is done by executing a document substantially in accordance with Exhibit C (by the authorized signatory of the Coordinating Member and the acceding Participating Member). The legal department of the Participating Member should review the document and determine whether accession to the registry is in accordance with the internal policy/rules of the Participating Member. In principle, modification of the INCbase Data Registry and Biomaterial Policy is not possible.

**Advantage:**

This document avoids the need for contracts at each data entry and data release.

Note: Data transfer or Material Transfer to external parties (those parties that have not signed an accession form) still requires a Data Transfer Agreement or a Material Transfer Agreement (by the Coordinating Member on behalf of the Partners who are represented by the Steering Committee).

 **INCbase**

**Data Registry and Biomaterial Policy**

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## Introduction and Scope

**The objectives of the INCbase Registry**

INCbase has multiple objectives including defining the variation of the CIDP phenotypes and their disease courses, improving current diagnostic criteria and clinimetrics, providing better understanding of the pathogenesis, discovering biomarkers of disease activity and develop a prediction model to determine the individual treatment response to IVIg and the need for long-term treatment of IVIg.

**Law and Regulations**

This Data Registry and Biomaterial Policy (“Policy”) is drafted taking into account EU law and legislation. As the INCbase Consortium is an international collaboration, it is not feasible to implement all national laws of the Participating Members into this INCbase Data Registry and Biomaterial Policy. In collecting Data and making available the Data to the INCbase Registry, each Participating Member requires to abide by its national law, including but not limited to privacy law. It is their individual responsibility to ensure that no Data is entered into the INCbase Registry in violation of their national law and legislation and that all Data can be used for the purposes of the INCbase Registry.

## 1. Definitions

1) In this INCbase Data Registry and Biomaterial Policy the following terms have the meanings ascribed to them below:

1. Access: Access to certain Datasets in accordance with Section 5.
2. Biobank: means a biobank located at the facilities of a Partner and owned by such Participating Member which biobank contains biological samples of one or more Donors.
3. Breach: means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored or otherwise processed.
4. Pseudonymised:  means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.
5. Controller: means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data
6. Data: The information collected from Donors stored in the INCbase Registry in Pseudonymised form. For the purpose of this Policy, Data are considered Personal Data.
7. Dataset: the Data from the INCbase Registry made available for the purpose of a Study.
8. Donor: Any individual whose Data are transferred to the INCbase Registry in compliance with the terms and conditions of this Policy.
9. Findings: Results, data and information, whether or not they can be protected, which are generated as a result of a Study.
10. Funds: the amounts raised by the INCbase Consortium for the development and maintenance of the INCbase Registry.
11. Participating Member: Each Participating Member of the INCbase Consortium.
12. Personal Data: means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
13. National Coordinator: A Participating Member coordinating the INCbase Consortium in a specific country.
14. Researcher: each Participating Member or third-party obtaining access to Data for Studies in accordance with **Section 8 subs 2-11**.
15. Sample: Each biological sample of a Donor that is stored in a Biobank and may be made available by the Participating Member for the purpose of the INCbase Registry.
16. Study: Any scientific research based on an authorized Study proposal involving Data.
17. Study Proposal: The document describing the scope, purposes and methodology of the Study.
18. Terms and Conditions: the INCbase Consortium Terms and Conditions for submitting, reviewing and approving Proposals.

## 2. The Registry

1. The INCbase Registry consists of a central database, populated with Data of Donors. All centers participate in the core module as outlined in the Study Proposal. Participation in extended modules is optional.
2. It is the intention that data of INC patients from EU member states and other countries are entered into the INCbase Registry in harmonized format with the aim for using the Data under this INCbase Data Registry and Biomaterial Policy.

It is anticipated that in time, other national CIDP registries are harmonized i) to allow data identical to the core module to be transferred into the INCbase Registry or ii) to link the national CIDP-registry to the INCbase Registry allowing access from a central interface.

1. The INCbase Registry may be linked to decentral biobanks owned by individual Participating Members.

## 3. Data collection and transfer to the INCbase Registry

1. Each Participating Member shall transfer into the INCbase Registry, on a non-exclusive basis, Data of patients that consented to participate in the Registry and that are eligible to participate in the INCbase Registry. Consent shall be obtained in accordance with applicable national law of the country of residence of the Donor.
2. Each Participant shall ensure that no direct identifiers are transferred into the INCbase Registry database. Each Participant shall keep the decoding key/decoding tables for the Data of each patient at a secured place at the facilities of the Participant. The decoding keys/decoding tables shall be maintained for at least the term of the existence of the INCbase Registry.
3. Transfer of Data into the INCbase Registry database and the use of such Data by the Participating Members in accordance with this INCbase Data Registry and Biomaterial Policy shall be free of charge. Costs for making available Data from the INCbase Registry to third-parties or in relation to activities under **Section 8, subs 13 and 14,** shall be determined by the Steering Committee. Where applicable, and dependent of available Funds, the INCbase Registry will contribute to costs of ethics review board and local monitoring.
4. The Data in the INCbase Registry shall be used for research purposes.
5. Each Participating Member shall remain the owner of the Data it transfers into the INCbase Registry. Transfer of Data into the INCbase Registry shall not restrict any use of such Data by the Participating Member that has contributed such Data.
6. It is the responsibility and liability of each Participating Member transferring Data into the INCbase Registry, to ensure such transfer is in compliance with their national law, including but not limited to privacy laws and that such Data can be used for the purposes of the INCbase Registry. As a consequence, if required by or if subject to a Participating Member’s national law or Institution policies, the terms and conditions of the INCbase Registry shall be submitted to a (ethical) review board, together with the informed consent forms and other relevant documents related to the INCbase Registry as determined by such review board.
7. To ensure the lawful processing of the Data by the INCbase Consortium, each Participating Member shall inform the Steering Committee of specific obligations following from its national mandatory law, that may affect the processing or use of the Data in relation to the INCbase Registry.
8. Data shall be made available from the INCbase Registry on behalf of the INCbase Consortium for Studies in accordance with **Section 8** hereof.

## 4. Samples

1. Participating Members shall determine in their sole discretion on a case by case situation whether they will make available Samples for a specific Study (“opt in” principle).
2. The Participating Members that intent to make available Samples for a Study shall, upon approval for the Study Proposal, conclude an MTA with the Participating Member and the Researcher that will perform the Study, based on the model MTA attached hereto as **Exhibit G**.
3. Each Participating Member that makes available Samples to a Researcher pursuant to sub 2 shall ship such Samples to the Researcher directly.
4. Shipment and receipt of Samples shall be the sole responsibility of the Participating Member and the Researcher.
5. If the Researcher is a Participating Member, the Participating Member making available and the Participating Member receiving the Samples may decide among them to use an alternative MTA or to waive the use of an MTA

## 5. Governance

1. The objectives of the governance structure are to:
	1. provide a sustainable infrastructure for standardized collection of data and Samples.
	2. ensure compliancy with the General Data Protection Regulation (EU) 2016/679 (hereinafter “GDPR”) and, with respect to Data originating from countries outside the European Economic Area, in accordance with such countries’ privacy law provisions;
	3. monitor registry activities and supervise conduct of the INCbase Registry, taking all reasonable steps to ensure credibility and integrity of the database;
	4. provide guidance for the review and coordination of publications prior to submission;
	5. ensure that research outputs are prepared and curated in a way which helps maximise their value to the INCbase consortium and the Participating Members;
	6. ensure that fair credit is given to the authors and to other individuals who have contributed significantly to the work that is described in each publication, report, or presentation.
2. The INCbase Registry recognizes the following governance bodies: the Steering Committee (SC), the Operational Management Team (OMT), a Scientific Advisory Board, and a stakeholders & advisory body (Inflammatory Neuropathy Consortium Board or INC-Board). One Participating Member shall act as the Coordinating Member of the INCbase Registry. National Coordinators shall each be responsible for coordinating the INCbase Registry activities in a specific country.

*Steering Committee*

1. The composition of the INCbase Registry Steering Committee is outlined in **Exhibit D**. The Steering Committee will be responsible for overall and financial management of the INCbase Registry on behalf of the Participating Members. More specifically, the Steering Committee is authorised by the Participating Members to and shall be responsible for:
	1. Governance and management regarding the INCbase Data collection;
	2. Approving to guidelines, specifications and Standard Operating Procedures;
	3. Publication of guidelines and SOPs on an INCbase Registry website;
	4. Informing the Participating Members on the progress of the INCbase Registry;
	5. Reviewing and approving Proposals in accordance with **Section 8** and the Terms and Conditions;
	6. Responsibility for transfer of biomaterials to laboratories (for separate INCbase projects only);
	7. Reviewing publications of results arising from the use of the Data by one or more Participating Members;
	8. Liaising and interacting with third parties providing services for the INCbase Registry, such as software and database developers, hosting services, etc..
	9. Liaising with third parties that provide Funds, unless decided otherwise on a case by case basis;
	10. Liaising and interacting with other currently running databases in the field of INC;
	11. Financial overview of infrastructure, including long-term financial sustainability;

*Operational Management Team*

1. The Operational Management Team consists of the Project Coordinator, and the Project Support Office. The Project Support Office consist of persons responsible for functional administration database, legal infrastructure and financial control. More specifically, the OMT will have the following tasks and responsibilities:
	1. Organization of quarterly SC meetings, including preparation of agenda and minutes.
	2. Organization of yearly INCbase Participating Member meetings.
	3. Support of local centers in the following: 1) Regulatory documents; 2) Obtaining national/local ethical review board; 3) Advice on privacy regulation; 4) Database access; 5) Customizing database; 6) Export of own data; 7) Erasing of data if appropriate.
	4. Export of composite data after approval of SC
	5. Adjustments of legal documents if appropriate
	6. Interacting with the database developer in maintenance and of central changes in database
	7. Financial control of Funds received from third parties for the INCbase Registry.
	8. Financial control of payments to Participating Members and subcontractors.

*Coordinating Member*

1. The Coordinating Member is authorised by the Participating Members to and shall be responsible for:
	1. concluding written agreements with regard to Funds received from third parties for the INCbase Registry.
	2. Agree with each National Coordinating Center on the tasks to be performed by the National Coordinating Center in its country.
	3. receiving, administer and allocate all Funds received for the INCbase Registry in accordance with the reasonable instructions of the Steering Committee.
	4. concluding written agreements with third parties providing services to the INCbase Consortium in relation to the INCbase Registry.
	5. concluding written agreements with scientific advisors based on the model agreement attached as **Exhibit F**.
	6. invoicing third parties on behalf of the INCbase Consortium and as instructed by the Steering Committee as appropriate.
	7. paying invoices received from third party service providers and other third parties in relation with any agreements executed by or for the INCbase Consortium in relation to the INCbase Registry as approved by the Steering Committee.
2. Coordinating Member shall not be liable for any breach of contract by a Participating Member of a contract concluded by Coordinating Member pursuant to **Section 5.5**.
3. Coordinating Member shall provide a copy of each contract concluded under **Section 5.5** to the Steering Committee, who will be responsible for making available such document to the Participating Members. Any contract or other document disclosed on the INCbase Consortium internet site, shall be considered to be made available to the Participating Members.
4. The Coordinating Member shall ensure transparent book-keeping in relation to the INCbase Registry’s financial administration and shall within 2 months upon each-fiscal year, prepare and share the financial accounting of the previous book-year.
5. Furthermore, the Coordinating Member shall be responsible for hosting the INCbase Registry database.
6. Pursuant to the decision-making procedures of the INCbase Consortium as outlined in **Exhibit D,** the Steering Committee may agree with the Coordinating Member on additional tasks.

*National Coordinating Centers*

1. National Coordinating Centers shall each with respect to their own country be responsible for the tasks agreed between them and the Coordinating Member and as outlined in the Letter of Authority a model of which is included in Exhibit E. Such responsibilities may include assisting the sites where appropriate in
	1. Obtaining all national licences and approvals, including to the extent required, approval from an ethics committee. Perform monitoring if required by national regulation or in case of participating in modules for which monitoring is required by the INCbase SC.
	2. other responsibilities agreed between the Coordinating Member and the National Coordinating Center as outlined in in **Exhibit E.**
2. National Coordinating Centers shall serve as national contact point between other Participating Members in the country of the National Coordinating Center and the Coordinating Member.

## 6. Database development, maintenance and management

1. Maintenance of the INCbase Registry shall be paid from Funds received. All proposed expenditures related to the INCbase Registry paid from the Funds shall require the prior approval of the Steering Committee. However, Coordinating Member shall only pay invoices from the INCbase Registry Funds to the extent Funds are available to cover such expenses. In no event shall Coordinating Member be responsible nor liable for paying any invoices or costs if these are not covered by the INCbase Registry Funding.
2. Coordinating Member shall be responsible for hosting the INCbase Registry.
3. Coordinating Member shall coordinate INCbase Registry database development, maintenance, modules and the INCbase website.

## 7. Privacy

1. Coordinating Member shall be responsible for hosting the INCbase Registry in accordance with the GDPR, as well as the instructions of the Steering Committee and Coordinating Member shall in this respect be considered a data Processor on behalf of the Participating Members.
2. The Participating Members consider this INCbase Data Registry and Biomaterial Policy and the processing of the Data in accordance with all national law. Each Participating Member shall promptly inform the Coordinating Member if it becomes aware that processing may be in violation with its national law, including of the nature and scope of the inconsistency. The Coordinating Member and the Participating Member will make a reasonable effort to jointly draft and propose terms that are consistent with the Participating Member’s national law. The Coordinating Member shall process the Data in accordance with **Exhibit A part 1**. Coordinating Member shall not be responsible or liable for any failure of a Participating Member to comply with its national law and/or institutional policies with regard to the transferring of Data into the INCbase Registry.
3. Participating Members shall ensure that the privacy of the Donors and the confidentiality of Data are protected in accordance with the statutory requirements applicable in their own country and the policies of the institution of which the Donor is a patient.
4. Participating Members shall transfer Data into the INCbase Registry in Pseudonymised form only, in accordance with the guidelines and instructions of the Steering Committee.
5. Each Participating Member is considered the Controller of its Participating Member Data and shall fulfil all obligations of Controller under applicable privacy law. The Participating Members shall be considered joint Controllers with regard to the aggregated Data in the INCbase Registry. The responsibilities of each joint Controller are outlined in Exhibit A part 2. Any processing of the Data contained in the INCbase Registry shall be in compliance with the GDPR and subject to section 7.2, national law of a Participating Member imposing further restrictions on the processing of the Data made available by such Participating Member.
6. The Steering Committee shall inform the Participating Members about the method of Pseudonymisation and the location of the INCbase Registry (and any changes to the location).
7. Prior to making available the Data for a Study, the Dataset to be transferred shall be given a new code.

## 8. Conditions for Access

*Op out principle*

1. The use of composite Data will be based on an opt-out principle. The Data of all Participating Members, required for Research will be made available, unless a Participating Member specifically opts-out.

*Access by Participating Members*

1. Each Participating Member remains the owner of its Participating Member Data in the INCbase Registry and is entitled to extract such Participating Member Data from the INCbase Registry database for its own uses without the approval of the Steering Committee. Such uses may include research in collaboration with other Participating Members involving their aggregated Participating Member Data. Each Participating Member shall be self-responsible and liable for any Processing of Participating Member Data it extracted from the INCbase Registry database or receives from another Participating Member. The Participating Member seeking collaboration with other Participating Members for a specific Study, shall inform the Steering Committee of its intention and make available to the Steering Committee the final Study Protocol.

*Access by Researchers*

1. Researchers shall be bound by this Policy. The applicable conditions must be made known to the Researcher at least prior to the review of the Study Proposal.
2. Researchers requesting Data shall submit their Study Proposal to the address shown on the INCbase Consortium website and in accordance with the Terms and Conditions.
3. Making available Data shall be conditional to obtained approval from, the Steering Committee and to the extent applicable to the permits and licenses required by the Researcher’s national law.
4. If the Steering Committee approves a Study Proposal, the Researcher will receive a ‘Letter of Approval’, stipulating the general terms and condition with regard to receipt and use of the Data, a signed copy of which must be returned to the Steering Committee prior to making the Data available.
5. The Researcher shall be considered a controller under the GDPR in relation to the Dataset. The Letter of Approval shall include provisions imposing on the Researcher the obligations to which Researcher must adhere under the GDPR with respect to the Dataset provided as a controller under GDPR.
6. The Steering Committee in its reasonable determination, following the advice of the advisors (mentioned in the Terms and Conditions) may set additional conditions to a specific Study. Such additional conditions will be communicated to the Researcher during the reviewing process and will be added to the Letter of Approval if the Study Proposal is approved.
7. Access to Data shall at least be conditional to the following:
8. The Researcher shall be responsible for obtaining the permits and approvals necessary in its own country and the policies of its institution.
9. The Researcher shall use the Data for the approved Study only. In case of deviations or changes in the Study the Steering Committee shall have the right to terminate Access without any liability at its sole discretion.
10. The Researchers shall bear sole responsibility for the handling and use of the Data in accordance with applicable law and legislation.
11. The Researcher shall not duplicate the Data or have them duplicated.
12. Except as may be necessary to support academic publication efforts, the Researcher shall not disclose or provide access to the Data to any third party without the prior written consent of Steering Committee.
13. The Researcher shall report the progress of the Study and Findings in a frequency as outlined in the Letter of Approval
14. Findings must be shared with the research community at large and therefore be scientifically published in accordance with the Terms and Conditions.
15. Researchers, conditional to the above, shall have access to the data free of charge.
16. Upon receipt of the Letter of Approval signed by the Researcher [and the fee mentioned in the Letter of Approval], the Data set necessary to perform the Study will be selected from the INCbase Registry and sent to the Researcher.
17. Participating Members and Researchers shall prior to the start of each Study agree in writing on ownership, access to and user rights of the Findings. The foregoing provided that the INCbase Consortium shall have a non-exclusive right to use the Data for the purpose of further research in the field of CIDP and development of professional and/or medical standards.

*Commercial Parties*

1. Commercial parties will not be provided access to the INCbase Registry or any individual Data derived from the INCbase Registry. However, companies that make available Funding may request certain analyses, based on an analyses plan developed by (a group of) Participating Members in the form of investigator-initiated research, with reports and/or scientific publication as sole deliverable.
2. In deviation of sub 13 above, commercial parties may be granted access to certain fully anonymised aggregated data, subject to all Participating Members involved in the Study agree and any additional conditions determined by the Steering Committee in consultation with such Participating Members.
3. In no event shall commercial parties own results of such analyses.

## 9. Authorship

The publication of Findings generated with Data from the INCbase Registry needs to comply with rules concerning authorship, as defined by the International Committee of Medical Journal Editors (ICMJE). To qualify as author, at least the following criteria apply to the contribution of the investigator in respect to the intended publication:

* 1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
	2. Drafting the work or revising it critically for important intellectual content; and
	3. Final approval of the version to be published; and
	4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

## 10. Ownership and Intellectual property rights

1. Without prejudice to the ownership of the Data by the Participating Members and ownership in any software used for the INCbase Registry, by any Participating Member or third party, the INCbase Registry shall be owned by the Participating Members jointly.
2. Without prejudice to the rights of each Donor in respect to its personal data under the GDPR and/or the rights of the Donor applying in its country of residence, no Participating Member can withdraw its Data from the INCbase Registry until the INCbase Registry is dissolved, unless it concludes that such withdrawal is justified based on pressing circumstances, such as mismanagement of the INCbase Registry, misuse of the Data or fraud.
3. The results of the Study including the intellectual property rights thereto shall be owned by the Researcher generating the same. Intellectual Study strategy shall be determined on a case by case basis, including possible compensation for commercial exploitation. The IPR strategy shall require prior assessment by and approval of the Steering Committee

## 11. Accountability

The Steering Committee shall on an annual basis report to the Participating Members the following:

* 1. the number of Participating Members, included patients
	2. the number of approved and rejected Studies;
	3. any organisational problems;
	4. Funds and expenses;
	5. Other, as the Participating Members may agree from time to time.

## 12. Donor complaints procedure

Complaints of Donors relating to or arising from the INCbase Registry shall be submitted to the institution of the Participating Member at which the Donor is a patient and/or where Data were collected.

## 13. Dissolving the INCbase Registry and Termination of Participation

 If the Participating Members determine that the INCbase Registry must be dissolved, the Steering Committee shall prepare a proposal that includes at least transfer, destruction or return of the Data. If the Data are maintained in another database after the INCbase Registry is dissolved, the proposal shall contain provisions for access and use of the Participating Members and third parties. Any transfer of Data into another database shall be in compliance with the terms of the GDPR.

If a Participating Member may terminate its participation in the INCbase Registry, it will inform the Chair of the Steering Committee of its intention. The withdrawing Participating Member and the Steering Committee shall in good faith discuss the consequences of such withdrawal. The foregoing provided that withdrawing Participating Member shall continue to grant the user rights under this Policy with respect to Data already entered in the INCbase Registry. No additional Data will be entered into the INCbase Registry by the Participating Member after the effective date of withdrawal. If the withdrawing Participating Member is a National Coordinator, such Participating Member shall cooperate with the Steering Committee in the proper transfer of its tasks and shall transfer to the Coordinating Member all documentation and information necessary for the effective implementation of the INCbase Registry activities and/or to be retained for the INCbase Registry under applicable law.

## 14. About this document

1. This Policy may be referred to as follows: INCbase Data Registry and Biomaterial Policy 2020©.

## 15. Liabilities and Warranties

Each Participating Member shall be responsible for the acts and omissions of its employees and agents to the extent permitted by law. This Agreement contains no promise of indemnification, express or implied, between the Participating Member. No Participating Member makes any express or implied warranties as to any matter, including the condition, originality or accuracy of the research or ownership, merchantability or fitness for a particular purpose of the research or any invention arising therefrom.

# EXHIBIT A: SPECIFIC DATA PROCESSING PROVISIONS

## PART 1: Responsibilities of the Data Processor

1. Background

Based on article 3 of the “INCbase Data Registry and Biomaterial Policy”, the Steering Committee has engaged the services of a data processor to hold and maintain the INCbase Registry Database and the Data contained therein.

1. Definitions
	1. In this Exhibit A, capitalised terms shall have the meaning defined in the INCbase Data Registry and Biomaterial Policy. Additional capitalised words shall have the following meaning:

|  |  |  |
| --- | --- | --- |
| a. | Incident | * + - 1. a complaint or request for information by a Donor with regard to the processing of Data by the Processor;
			2. an investigation or confiscation of Data by government officials or a suspicion that such may occur at some point in the future; and/or
			3. a personal data breach as meant in Article 4.12 of the GDPR.
 |
| b. | Sub-Processor | Any non-subordinate third party hired by the Processor to help process Data. |
| c. | Processor | The Processor within the meaning of Article 4.8 of the GDPR. |
| d. | Controller | Each of the Joint Controllers within the meaning of Articles 4.7 and 26 of the GDPR. |

1. The processing of the data
	1. The Processor shall only process Data on behalf of the Controller for the purposes outlined in the INCbase Data Registry and Biomaterial Policy and in accordance with the instructions of the Steering Committee.
	2. The Processor shall notify the Steering Committee at once if Processor feels that said instructions constitute a violation of applicable law.
	3. Without prejudice to the provisions of Article 3.1, the Processor shall be allowed to process Data if it is required to do so by a statutory provision (including the court order or administrative decisions based on it). In such cases, the Processor shall to the extent permitted by law, notify the Steering Committee of the intended processing of the Data and of the statutory provision prior to the processing. The Steering Committee shall inform the Participating Member(s) whose Data are affected forthwith. Processor shall minimise the extent of the enforced processing to the maximum extent possible.
	4. The Processor shall process the Data in a proper and meticulous manner, in accordance with the requirements to which it is subject under the GDPR and to the extent known to the Processor, the national privacy law of the Participating Members.
	5. In processing the Data, the Processor shall reasonably ensure that its procedures shall not violate health care legislation.
	6. The Processor shall not process Data or have Data processed in countries outside the European Economic Area (‘EEA’), unless so instructed by the Steering Committee.
2. The security and monitoring of Data
	1. To protect the Data from loss, unauthorised inspection, damage or any other form of unlawful processing, and to guarantee the availability of the Data when due, the Processor shall implement appropriate and effective technological and organisational measures, which, considering the current state of the art and the costs associated with it, shall be in accordance with the nature of the Data to be processed. These security measures shall include the following:
		1. measures designed to guarantee that only authorised employees can access the Data for the purposes outlined;
		2. measures involving the Processor only granting its employees and Sub-Processors access to Data through individual named accounts, with the use of said accounts being adequately logged and with the accounts concerned only granting their users access to those Data whose access is necessary for the legal person concerned;
		3. measures designed to protect the Data from unintentional or unlawful destruction, unintentional loss or changes and unauthorised or unlawful retention, processing, access or disclosure;
		4. measures designed to identify weaknesses with regard to the processing of Data in the systems used to provide services to the Controllers;
		5. measures designed to guarantee that Data are separated in a sensible manner from the Data the Processor processes on its own behalf or on third parties' behalf;
		6. other measures agreed between the Steering Committee and the Processor.
	2. The Processor's security measures shall comply with the requirements of the GDPR. Furthermore, the Processor has implemented an appropriate, written security policy for the processing of the Data.
	3. Upon the request of the Steering Committee and provided that such certificate is in place, the Processor shall submit a certificate issued by an independent and competent third party that shows that the Processor's methods comply with the requirements arising from this article 4.
	4. The Steering Committee is entitled to monitor (or have monitored) the Processor's compliance with this article 4 and shall enable the Steering Committee to inspect the Processor's processing methods at the reasonable request of the Steering Committee, but no more frequent than once per year, unless the Steering Committee has reasonable doubts that the Data are processed in accordance with the INCbase Data Registry and Biomaterial Policy, this Exhibit and applicable law.
	5. If, in response to such inspection, the Steering Committee reasonably instructs the Processor to adjust or update its security policy, the Processor shall reasonably comply.
	6. The Processor shall ensure that persons authorised to process the Personal Data on its behalf, have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality
3. Obligation to provide information and incident management
	1. When an Incident occurs, has occurred or may be about to occur, the Processor shall to the extent reasonably possible, undertake the activities necessary to undo the damage caused by the Incident as soon as possible or minimise the consequences to the maximum extent possible.
	2. In addition, the Processor shall notify the Steering Committee without undue delay and to provide any relevant information on:
4. the nature of the Incident;
5. the Data that (may) have been affected;
6. the actual and likely consequences of the Incident; and
7. the measures which have been or will be taken to resolve the Incident or to minimise the consequences or damage to the maximum extent possible.
	1. The Processor shall consult the Steering Committee on further arrangements to be undertaken with respect to the Incident and to prevent future Incidents.
	2. The Processor shall cooperate with the Steering Committee at any time, shall follow the reasonable instructions of the Steering Committee and shall enable the Steering Committee to conduct an appropriate investigation of the Incident, formulate a response to the Incident and take appropriate subsequent steps, including notifying the Dutch Data Protection Authority and/or the Donor.
	3. The Processor shall at all times have written procedural guidelines in place covering the handling of Incidents and shall furnish the Steering Committee with a copy of such procedural guidelines upon the request.
	4. Alerts under this article 5 shall be addressed to chair of the Steering Committee or any other designee indicated by the Steering Committee.
	5. The Processor shall not provide third parties any information on Incidents, except in cases where the Processor is legally required to do so or the Parties have otherwise agreed.
8. Obligation of cooperation
	1. The Processor shall fully cooperate with the Steering Committee to enable the Steering Committee and each Participating Member to fulfil their obligations under the GDPR. The Processor and Steering Committee shall agree on procedures to comply with the rights of Donors under the GDPR.
9. The hiring of Sub-Processors
	1. The Processor shall not adding the processing of Data to a Sub-Processor without prior written permission from the Controller. The foregoing does not apply to the Sub-Processors listed in Annex 1 to this Exhibit A.
	2. If the Controller agrees to the hiring of a Sub-Processor, the Processor shall impose on the Sub-Processor the same requirements under this Exhibit A and legislation.
	3. The Processor shall remain fully responsible for the processing of the Data by the Sub-Processor as if it has performed the processing itself.
10. Costs
	1. Without prejudice to the remuneration for the services provided by the Processor under the INCbase Data Registry and Biomaterial Policy, the Processor is entitled for compensation of costs incurred for any form of support or any other additional service the Processor will be required to provide under this Exhibit A.
	2. The preceding provision shall not apply if the duties to be performed are related to a shortcoming attributable to the Processor under this Exhibit A.
11. Duration and termination
	1. This Exhibit A shall enter into force on the effective date of the INCbase Data Registry and Biomaterial Policy and terminate upon dissolvement of the Registry or so much earlier as foreseen in the INCbase Data Registry and Biomaterial Policy or this Exhibit A.
	2. Obligations which, by their very nature, are meant to continue to apply even after the termination of this Exhibit A shall continue to apply after the termination of this Exhibit A. Such provisions shall include those which arise from provisions governing confidentiality, liability, dispute resolution and applicable law.
	3. Either Party shall be entitled to terminate the activities of the Processor in relation with the INCbase Registry upon 30 days written notice.
	4. Upon termination of the services of the Processor in relation to the INCbase Registry, the Processor shall fully cooperate with the Steering Committee to transfer the INCbase Registry to a third party or to destroy the Data as instructed by the Steering Committee.
12. Retention period, restoration and destruction of Data
	1. The Processor shall not retain the Data longer than strictly necessary for the services under the INCbase Data Registry and Biomaterial Policy and applicable law.
13. Intellectual property rights
	1. If the (collection of) Data is protected by any intellectual property rights, the Processor is herewith granted permission to process the Data as foreseen in the INCbase Data Registry and Biomaterial Policy.

## Part 2: Joint Controller Responsibility Matrix

|  |
| --- |
| The members of the INCbase Registry are joint controllers with respect to the personal data of the Donors processed in the INCbase Registry. Based on article 26 of the GDPR they require to document their respective responsibilities under the GDPR. This Joint Controller Responsibilities Matrix forms an integral part of the INCbase Data Registry and Biomaterial Policy  |
| **Data Protection Responsibilities** | **Responsible Party.**  |
| 1. **Compliance with article 13 / 14 GDPR regarding information to be communicated to the data subjects.**
 | Each Member has the responsibility to inform their patients on the processing of their personal data under the Registry. |
| 1. **Compliance article 6 GDPR, informed consent or other legal ground for processing of the patients’ personal data**
 | Each Member has the responsibility to inform their patients and obtain their consent under article 6.1.a GDPR prior to entering any personal data of the patient into the registry. |
| 1. **Compliance with articles 15 to 18 and article 21 GDPR, rights of the data subject.**
 | The personal data in the Registry are pseudonymized. The party/ies responsible for data management do not have access to directly identifiable information and are not allowed to attempt to identify any patient in the registry. Therefore, any request under articles 15-18 and 21 GDPR shall be referred to the hospital of the patient. The parties shall collaborate in providing all assistance necessary to enable the Participating Member to comply with its obligations under GDPR and subsequent national law.  |
| 1. **Compliance with Data portability in article 20 GDPR.**
 | Same as under 3 above. |
| 1. **Warrant security of the personal data in the Registry in compliance with article 32 GDPR.**
 | Each Participating Member is responsible for maintaining technical and organizational measures at site prior to entering the personal data into the Registry. Each Participating Member is responsible for maintaining the secrecy of any log-in (login ID and password) made available to access the data of the patients they entered into the Registry. The Participating Members are jointly responsible for the security and safety of the registry database and the personal data therein, they have mandated this responsibility to the Steering Committee who has – in agreement with the Participating Members – assigned management of the database and data management to a processor on behalf of the members. The processor[[1]](#footnote-2) has the responsibility to ensure the registry database is sufficiently protected by technical and organizational measures.  |
| 1. **Compliance with information obligations to authorities and data subjects in relation to personal data breaches pursuant to articles 33 and 34 of the GDPR.**
 | In case of a personal data breach incurred by a Participating Member, such member shall inform the Coordinating Member if the Registry data are affected. In case of a personal data breach occurring in respect of the Registry database. The processor for the members shall inform the Coordinating Member without delay and the Coordinating Member shall inform the Steering Committee, and the respective Participating Members. The Participating Members shall give each other such assistance as needed to enable each other to comply with applicable law and shall consult each other in relation to informing the authorities and the data subjects concerned.  |
| 1. **Ensure that personnel having access to the personal data are instructed in accordance with article 29 GDPR and that they are bound to confidentiality under a contract. Ensure compliance with these requirements by their personnel**
 | Each Participating Member has the obligation to instruct and bind their personnel having access to the personal data. The processor on behalf of the Participating Members has contractual provision in place in all labor contracts binding personnel to confidentiality  |
| 1. **Warrant that processors engaged by each member are contractually bound in accordance with article 28 GDPR. Monitor compliance of the processors with such contract**
 | Data management in relation to the Registry is assigned to the processor on behalf of the Participating Members and is contractually bound to comply with article 28 GDPR. Each Participating Member engaging a processor for its own processing of personal data in relation to the registry has the obligation to comply with article 28 of the GDPR and applicable national law.  |
| 1. **Warrant that transfer of data outside the EEA is in compliance with the GDPR and that sufficient safeguards are in place to ensure safe and lawful processing.**
 | Personal Data of the Donors may be transferred for research projects outside the EEA. Such transfer shall include a data transfer agreement and if applicable the Binding Corporate Rules of Contractual Clauses. All transfer shall be in accordance with the provisions of the INCbase Data Registry and Biomaterial Policy, including assessment of an appropriate research plan. |
| 1. **Warrant the performance of a Privacy Impact Assessment (PIA) in accordance with article 35 GDPR**
 | The AMC has performed a PIA on the registry and will perform the PIA every 3 years in accordance with internal AMC policy. This is however without prejudice of each member to perform a PIA in accordance with its processing of the Personal Data in relation to the Registry pursuant to the GDPR and national privacy law. The Participants are advised to repeat the PIA every 3 years.  |
| 1. **Archiving and destruction of personal data**
 | The personal data in the Registry shall be stored and processed in accordance with the terms of the INCbase Data Registry and Biomaterial Policy.  |
| 1. **Other responsibilities of the parties in respect of privacy protection**
 | Not applicable, if future changes in law or practice require amendment of this Exhibit and privacy protection provisions, the Members will jointly determine the necessary amendments.  |

# EXHIBIT B: CERTIFICATE OF AUTHORITY

The Steering Committee of the INCbase Consortium, pursuant to the “INCbase Data Registry and Biomaterial Policy” dated 1 August 2019, hereby authorises the Academic Medical Center Academisch Medisch Centrum, with its address at Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands (“AMC”) to represent the INCbase Consortium vis-à-vis third parties and to negotiate and execute agreements with third parties including but not limited with respect to funding, research, consultancy and data management.

Subject to Section 3 of the INCbase Data Registry and Biomaterial Policy, the Steering Committee of the INCbase Registry acknowledges and agrees that AMC shall administer the funds received from third party funders and shall be entitled to make third party payments from such funds in accordance with the INCbase Data Registry and Biomaterial Policy. AMC shall only pay such third-party payments to the extent INCbase Consortium allocated funds are available at the AMC bank accounts.

This Certificate of Authority is effective from 1 January 2019 and will remain effective until the expiry or early withdrawn by the Steering Committee, whichever occurs first.

January 1, 2019



Name: F. Eftimov

Title: Chair of the Steering Committee of the INCbase Consortium

**EXHIBIT C: DECLARATION OF ACCESSION**

Declaration of accession of a new Participating Member to the INCbase Registry (the “INCbase Registry”)

In accordance with the “INCbase Data Registry and Biomaterial Policy”, the Steering Committee of the INCbase Consortium hereby welcomes **[NAME Participating Centre]**, [ADDRESS Participating Centre], legally represented by [NAME + Title],  as a Participating Member of the INCbase Consortium.

**[NAME new Participating Centre]** hereby consents to become a Participating Member to the INCbase Registry and accepts all the rights and obligations of a Participating Member as outlined in the INCbase Data Registry and Biomaterial Policy, starting from the Accession Date [date].

Due to the legal merger of the Academic Medical Center (AMC) and VU Medical Center (VUmc) into Stichting Amsterdam UMC per 1 January 2024, references to AMC in the INCbase Data Registry and Biomaterial Policy shall refer to Amsterdam UMC.

This Declaration of Accession has been executed in 2 originals, duly signed by the undersigned authorized representatives.

**[NAME new Participating Centre],**

Signature(s)
Name(s)
Title(s)

[Date and Place]

Acting on behalf of the INCbase Consortium in accordance with Section 5 of the INCbase Data Registry and Biomaterial Policy, **Stichting Amsterdam UMC,** having its registered office and principal place of business in at De Boelelaan 1117, 1081HV Amsterdam, the Netherlands, represented by its wholly owned subsidiary **Amsterdam UMC Medical Research B.V.** legally represented by its CFO, J.J. Brand.

Signature(s)
Name
Title(s)

[Date and Place]

Read and acknowledged:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Principal Investigator of Participating Member

# EXHIBIT D: DECISION MAKING PROCEDURES

**Preliminary set up**

***Steering Committee (SC)***

**SC Members**

The SC shall consist of the following members: a representative of the Coordinating Member (chair), Filip Eftimov and 8 extra board members from among the Participating Members (hereinafter referred to as “SC member”). The eight extra SC members shall be from at least 6 different Participating Members in 6 different countries.

The SC will meet at least three times per year to discuss progress of the Registry.

The SC shall report to the Participating Members by news letters and provide a general update once per year at the Peripheral Nerve Society Meeting

**Preparation and organisation of SC meetings**

Convening meetings:

The chairperson of the SC shall convene meetings of the SC at least three times a year and at any time upon written request of at least three of the SC members.

Notice of a meeting:

The chairperson of the SC shall give notice in writing of a meeting to each SC member as soon as possible and no later than 14 calendar days for ordinary meetings and 7 calendar days for extraordinary meetings.

Sending the agenda:

The chairperson of the SC shall prepare and send each SC member a written (original) agenda no later than 7 calendar days preceding the meeting.

Adding agenda items:

Any agenda item requiring a decision by the SC members must be identified as such on the agenda.

Any member of the SC may add an item to the original agenda by written notification to all of the other members up to the minimum number of 2 working days preceding the meeting.

Any decision may also be taken without a meeting if the Coordinating Member circulates to all SC members a written document which is confirmed by e-mail by the defined majority of all SC members.

Meetings of the SC may be held by teleconference or other telecommunication means.

Decisions will only be binding once the relevant part of the minutes has been accepted in accordance with this Exhibit D.

**Voting rules and quorum in the SC**

The SC shall not deliberate and decide validly unless two-thirds (2/3) of its members are present or represented (quorum).

Each SC member present or represented in the meeting shall have one vote.

Defaulting Parties may not vote.

Decisions of the SC shall be taken by a majority of two-thirds (2/3) of the votes.

**Minutes of SC meetings**

The chair of the SC shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He shall send the draft minutes to all SC members within ten (10) calendar days of the meeting.

The minutes shall be considered as accepted if, within 15 calendar days from sending, no SC member has objected in writing to the chairperson with respect to the accuracy of the draft of the minutes.

The chairperson shall send the accepted minutes to all the SC members and Participating members.

**The Operational Management Team (OMT)**

The OMT consists of the chair of the SC, one extra SC member, and the INCbase coordinating researcher.

# EXHIBIT E: MODEL LETTER OF AUTHORITY NATIONAL COORDINATING CENTERS

Letter of Authorization INCbase Registry

Academic Medical center, having its address at Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands (“AMC”)

TO WHOM IT MAY CONCERN

Subject to Section 5.5 and Exhibit B of the INCbase Data Registry and Biomaterial Policy, the AMC herewith authorises [name member, address] to act National Coordinating Center in accordance with section 5.6 of the INCbase Data Registry and Biomaterial Policy, and to represent the INCbase Consortium and act in its own name and responsibility towards third parties and to bind the INCbase Consortium, for the following purposes:

* Assisting in selecting qualified hospitals and physicians to participate in the INCbase Consortium.
* serve as contact point between other Participating Members and the Coordinating Member
* National submission of het Study documentation and amendments to the ethics committee, independent review board and appropriate authorities.
* Assisting Participating Members in local submission of the Registry documentation and amendments.
* Performing monitoring activities, including source data verification.
* Adapting the national Informed Consent Form as appropriate.

The delegation of the tasks shall be effective in the following country/ies:

[list of country/ies]

This letter of delegation takes effect on [effected date]

The delegated duties are without the right to subcontract. The letter of delegation shall be effective until the termination of the INCbase Registry, unless this Letter of Delegation is withdrawn by the National Coordinating Center, whichever date is the first.

Yours sincerely,

Academic Medical Center

Dr. F. Eftimov

Read and accepted:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
On behalf of National Coordinating Center

# EXHIBIT F: CONFIDENTIALITY AGREEMENT

**This Agreement is made by and between the** UNDERSIGNED:

AMC Medical Research B.V. on behalf of Academic Medical Center, acting for and on behalf of the INCbase Consortium, having its principal place of business at Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands, The Netherlands, lawfully represented in this matter by prof. dr. M.J.A.P. Daemen, CEO

Hereinafter referred to as “[Coordinating Member]”,

and

, acting for itself and having an address at

Hereinafter referred to as “Advisor”

Hereinafter individually referred to as “Party” and collectively as “Parties”.

RECITALS

* The INCbase Consortium is composed of [disciplines], institutions and others motivated to carry out excellent clinical and biological research in the field of INC and collaborate with colleagues around the world;
* [Acronym] is the legal entity that on behalf of the Steering Committee of the INCbase Consortium is authorized to enter into third party agreements in matters concerning the INCbase Registry;
* The Advisor is an expert in the field of ; and
* The INCbase Consortium wishes to retain the Advisor to [purpose] (the “Purpose”).

NOW, THEREFORE, in consideration of the Advisor receiving information for the Purpose, which is of a confidential nature, the Parties hereby agree as follows:

1. For the purpose of this Confidentiality Agreement (the “Agreement”), "Confidential Information" shall mean information disclosed in whatever form by or on behalf of the INCbase Consortium and/or [Acronym] to Advisor under this Agreement, which information includes but is not limited to imaging materials, which imaging materials may include or be accompanied by personal data as defined in Regulation EU 2016/679.

1. The Advisor in each case shall keep the Confidential Information in confiden­ce and will not use the same except for the Purpose. Accordingly, the Advisor will not publish or otherwise disclose the Confidential Information received without the prior written consent of the INCbase Consortium’s Steering Committee.
2. Notwithstanding clause 2 above, the Advisor may give access to the INCbase Consortium and/or [Acronym]’s Confidential Information to those employees or co-workers (the “Co-Advisors”) who have a need to know to such Confidential Information for the Purpose and who have been instructed of the restrictions imposed on the Advisor pursuant to this Agreement and who have agreed to abide by such restrictions. It is the responsibility of the Advisor to make sure that any and all Co-Advisors will be advised of and will abide to the conditions of this Agreement.
3. The Advisor’s obligations of confidentiality and non-disclosure pursuant to this Agreement shall however not apply to information and data:
4. which was already in possession of the Advisor at the time of receipt hereunder, as evidenced by their written re­cords; or
5. which was at the time of receipt or there­after becomes publicly available otherwise than in breach of any obligati­on he­reun­der; or
6. which the Advisor has received from a third party who is legally entitled to disclose the same; or
7. which was independently developed by employees of the Advisor without reference to the Confidential Information, as evidenced by the Advisor's written records; or
8. which is required by law, regulation or order of a competent authority (including any regulatory or governmental or securities exchange) to be disclosed.
9. The Advisor will maintain reasonable security with respect to said Confidential Information.
10. [Acronym] and the INCbase Consortium Steering Committee warrant that they have the rights to disclose the Confidential Information to the Advisor.
11. Upon the completion of the Purpose or at the request of INCbase Consortium Steering Committee at any time during the term of this Agreement, the Advisor shall discontinue the use of and shall promptly return all Confidential Information and will promptly return all documentation and/or other information carriers embodying that Confidential Information.
12. This Agreement shall be effective from the date of final signature and terminates upon completion of the Purpose, provided that each Party may terminate this Agreement upon written notification to the other Party. The obligations of confidentiality shall survive the expiry or termination of this Agreement.
13. This Agreement shall be governed and enforced in accordance with the Laws of The Netherlands without regard to its conflict of law provisions. All disputes arising in connection with this Agreement shall exclusively be submitted to the competent courts in Den Haag, The Netherlands.

*[signatures on the next page]*

THUS AGREED UPON, SIGNED AND EXECUTED IN **TWO** COUNTERPARTS

**AMC Medical Research**

Signature: …………………………………… Signature: ……………………………………

Name: …………………………………… Name: ……………………………………

Title: …………………………………… Title: ……………………………………

Date: …………………………………… Date: ……………………………………

# EXHIBIT G: MODEL MATERIAL TRANSFER AGREEMENT

*(this MTA is not mandatory, each Participating Member is entitled to use its own model, provided such model is not in violation with the rights of the INCbase Registry Members in relation to the use of the Recipients use of the Registry Data)*

**Material transfer agreement**

This Agreement becomes effective on [insert date] (the “Effective” Date) by and between

[add name provider], with principal place of business at [add full address], legally represented by [insert name and title]

*hereinafter referred to as “Provider”*

and

[add name recipient], with principal place of business at [add full address], legally represented by [insert name and title authorized representative]

*hereinafter referred to as “Recipient”*

**Preamble**

1. Provider participates in the INCbase Consortium. INCbase Consortium is a collaboration between medical centres worldwide, and is established with the aim to facilitate scientific research and among others, by making available data from its registry to researchers;
2. Recipient is a [for profit or non-profit] organization that wishes to make use of certain clinical data from the Registry and in addition require samples from the same subjects to perform the project attached to this agreement as Attachment A; and
3. Provider is entitled and willing to make available such materials to Recipient under certain terms and conditions.

Therefore the Parties agree as follows:

1. **Definitions**
	1. *Affiliate*
	Any firm, corporation or other entity controlling, controlled by or under common control with either of the Parties and for such purpose "control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the voting interest in such firm, corporation or other entity or the power to direct the management of such firm, corporation or other entity.
	2. *Agreement*
	This Agreement and its existing and future attachments, which form an integral part of the Agreement.
	3. *Applicable Law*
	Any international and national laws and regulation governing the processing of human tissue samples under this Agreement, which include privacy laws of the country of residence of the Subject.
	4. *Background Information*

 Means any data, information and know-how which are held by a Party on or after the Effective Date, and all copyrights or other Intellectual Property Rights pertaining to such data, information and/or know-how which is not Foreground Data, which Background Information may be made available and used in accordance with the terms of this Agreement.

* 1. *Coded*

 Processed through reliable and safe information and communication technologies, in such manner that the Recipient cannot, without disproportional efforts, identify any individual Subject involved.

* 1. *Confidential Information*
	Any information and/or data proprietary or possessed by Provider except the Samples and the Clinical Data, irrespective of its form (oral, visual, written, electronic or otherwise) which is disclosed by or on behalf of Provider to recipient pursuant to this Agreement, whether of a technical, business or other nature and any information relating to a recipient or its Affiliates’ trade secrets, products, designs, technologies, promotional material developments, methods of manufacture, research, proprietary rights or business operations including but not limited to business or research plans, business or research strategies, marketing plans.
	2. *Commercial Gain (or Profit Making)*
	Company’s sale, lease, license, or transfer of the Samples or Modifications, Progeny and Unmodified Derivatives to a for-profit organization. Commercial Purposes shall also include uses of the Samples or Modifications, Progeny and Unmodified Derivatives by any organization, including Company, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Samples or Modifications, Progeny and Unmodified Derivatives to a for-profit organization.
	3. *Foreground Information*
	All information, materials and data, whether patentable or not, generated from the use of the Samples in the Project, explicitly excluding the Samples per se and explicitly excluding Progeny and Unmodified Derivatives.
	4. *INCbase Consortium*The collaboration between hospitals worldwide in establishing and maintaining a registry of data from patients suffering from CIDP.
	5. *Incidental findings*Unexpected findings resulting from the activities carried out in accordance with the Project Plan, and related to Samples, which findings may be of direct clinical relevance to the health of a particular Subject or its direct relatives.
	6. *Informed Consent*The written, signed and dated consent from the Subject or its lawful representative, based on sufficient and understandable information, covering for the collecting, storage use and cross border transmission or access and Modification of its Samples.
	7. *Intellectual Property Rights or IPR*

 Patents, trademarks, trade names, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect and which may subsist anywhere in the world, whether or not any of registered and including applications for registration.

* 1. *Modifications*New substances created by Recipient, which contain/incorporate or are derived from the Samples, but are not Progeny or Unmodified Derivatives.
	2. *Party*Each individual Party named first above and “Parties” shall mean such individual Parties jointly.
	3. *Permitted Use*The purpose for which the Samples are made available to Recipient under this Agreement which purpose is limited to those described in Section 4.
	4. *Progeny*
	Unmodified descendant from the Samples, such as virus from virus, cell from cell, or organism from organism.
	5. *Project*The research activities performed by Recipient as outlined in the Project Plan.
	6. *Project Plan*The document describing the analyses and research activities to be undertaken by Recipient and the justification for its use of the Samples. Amendments to the Project Plan will be considered as part of the Project Plan.
	The Project Plan is attached to this Agreement as Attachment A.
	7. *Recipient*Includes any employee involved in the performance of the Project receiving Samples pursuant to this Agreement.
	8. *Review Committee(s)*Any ethics committee(s) or review board(s) lawfully authorized to review and approve the Project Plan prior to making available or use the Samples for the purpose of this Agreement.
	9. *Samples*The biological human samples obtained from Subjects and made available by Provider or on behalf of the medical centres collaborating in the INCbase Registry pursuant to this Agreement. Samples shall be of the type and in the amounts listed in Attachment B, and include any progeny, derivate and/or modifications of such biological human samples.
	10. *Security Breach*Any unauthorized or accidental use, access or processing Samples.
	11. *Subject*The individual from whom the Samples originate.
	12. *Unmodified Derivatives*Substances created by Recipient which constitute an unmodified functional subunit or product derived from or expressed by the Samples, including without limitation sub clones of unmodified cell lines, antibodies, DNA, RNA, or purified or fractionated subsets of the Samples.
1. **Representation**
	1. The Parties represent that they are authorized to enter into this Agreement and that this Agreement does not and to their reasonable knowledge will not conflict with any other right or obligation provided under any other agreement or obligation that it has with any third party.
	2. The Parties agree to abide by their respective national laws. It shall be the responsibility of each Party to effect and maintain all registrations for the processing of Samples that are required by its national law.
	3. Provider represents that it has obtained Informed Consent from each Subject in accordance with its Applicable Law, which Informed Consent allows transfer of Samples to Recipient for the purposes of the Project.
2. **Approvals and shipment/transfer**
	1. Provider’s obligation to transfer the Samples, is conditional on the fulfilment of the following:
		1. Recipient has received initial confirmation of the Steering Committee of INCbase for the Project and the formal approval from the Steering Committee is conditional to the receipt of the Samples.
		2. Recipient has submitted the Project Plan to Provider for Provider’s review and approval and assessment by the relevant Review Committee(s);
		3. The Review Committee(s) has approved the Project Plan including the transfer of the Samples to Recipient; and
		4. To the extent mandatory by Applicable Law or as instructed by the Review Committee, amendments to the documentation indicated in 3.1.a above will be submitted and prior approved by the Review Committee(s);
		5. All required other national, local and/or institutional approvals and mandatory licenses in relation to the execution of any aspect of the Project Plan, including - as applicable - import and/or export licenses, are obtained in accordance with Applicable Law.
		6. Receipt by provider of Payment.
	2. Upon fulfilment of all conditions set forth in Section 3.1. Provider shall transfer to the Recipient the Samples listed in Attachment B.
	3. The Samples are provided ‘as is’ and without warranty of fitness for a particular purpose of any other warranty of any kind, express or implied.
3. **Permitted Use**

Recipient shall use the Samples only for the purposes of performing the Project in compliance with Applicable Law and in accordance with the approved Project Plan.

1. **Restrictions and specific obligations of Recipient**
	1. Recipient shall not give access or transfer the Samples, in whole or part, to any third party without Provider’s prior written consent and shall not give access to any identifiable data derived from the Samples. The Recipient shall refer any request from third parties for transfer of or access to Samples to Provider.
	2. Recipient shall not permit the transfer of the Samples or any portion thereof to any facility of Recipient, other than the facility/facilities identified in Attachment B.
	3. Recipient acknowledges that it shall not have or be allowed to grant ownership or any other proprietary interest in the Samples. Recipient shall use neither the Samples nor any Modification nor any Progeny or Unmodified Derivatives for any profit making or commercial gain. Recipient shall not use the Samples in human or animal subjects.
	4. Recipient shall not generate Modifications, other than those explicitly described in the Project Plan, if any and only to the extent they are covered by the Consent.
	5. Recipient acknowledges that Subjects - and/or their legal representatives on their behalf - may withdraw or change their initial Informed Consent. Provider shall promptly notify Recipient of any withdrawal or changes in the Informed Consent of a Subject, which may affect the use of such Subject’s Samples under this Agreement. Recipient shall follow the instructions of the Provider in the handling and/or disposal of the respective Samples.

 To the extent required for the purpose of the Project, Provider shall make reasonable efforts to replace the withdrawn Samples with those of a new Subject.

Recipient agrees to use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Samples. Recipient shall store the Samples promptly in accordance with the storage instructions of the Provider and in compliance with its national Law.

1. **Privacy, Security and Protection**
	1. Recipient and Provider shall be responsible for its processing of Samples in accordance with Applicable Law.
	2. Provider shall make available Coded Samples only and in accordance with the Informed Consent. Provider shall keep decoding tables if required by and in accordance with Applicable Law or as mandatory by its institutional internal policies. Recipient shall refrain from any form of tracing and/or identifying any Subject through the Samples. In the event any Subject, for whatever reason, becomes identifiable to Recipient, Recipient agrees to preserve, at all times, the confidentiality of information pertaining to such Subjects. Recipient shall notify Provider forthwith of any such identification and shall follow any instructions from Provider as to how to redress or mitigate any adverse consequences for the Data Subject and/or Provider of such identification.
	3. Samples received pursuant to this Agreement shall be stored in a safe and secured place at facilities controlled by the Recipient.
	4. Recipient shall be responsible and liable for the handling of the Samples

in its custody in accordance with this Agreement and the Project Plan. Recipient agrees that it and its employees and legal representatives are covered by applicable privacy legislation and its duties thereunder.

* 1. The Recipient shall adopt appropriate technical and organizational measures to prevent any Security Breach. Provider reserves the right to request and inspect Recipient sample and data security and management documentation to ensure the adequacy of sample and data protection measures. Recipient shall promptly inform the Provider of any Security Breach and shall take all reasonable actions necessary to remedy such Security Breach.
	2. Recipient shall limit access to and processing of the Samples to those employees or other authorized representatives of Recipient who have a need to process them under the Project and under Recipient’s direct supervision and who are bound by written confidentiality obligations with respect to the processing of the Samples and the receipt of Confidential Information that are no less onerous than those set forth in this Agreement.
	3. Each Party shall ensure that the security, integrity and quality of the Samples are maintained at all times. Each Party shall be responsible for maintaining its own chain of custody to allow traceability and management of the Samples.
	4. In the event the Samples are made available to Recipient subject to any Subject’s restrictions, Recipient hereby assumes the obligation to abide by these restrictions as Recipient’s own obligation towards the Subject. Recipient agrees that Subjects can enforce such restrictions as well as any pertinent provisions of this Agreement as third-party beneficiaries and, in the event they choose to do so, that Recipient will not object to Subjects’ being represented by an association or other bodies if they so wish. Recipient acknowledges that a Subject who has suffered damage(s) as a result of any violation by Recipient of pertinent provisions in this Agreement or of Applicable Law, may be entitled under Applicable Law to receive compensation from Recipient for the damage(s) suffered. Recipient acknowledges that, in the event of such a violation, the Subject may bring an action before a court within the Subject’s jurisdiction against Recipient.
1. **Confidentiality**
	1. Recipient shall not disclose to third parties, nor use the Confidential Information of Provider Disclosing Party for any other purpose than Permitted Use, without the prior written consent of Provider, except as provided pursuant to this Agreement.
	2. The above provisions of confidentiality shall not apply to that part of Confidential Information, which Recipient is able to demonstrate by documentary evidence:
		1. is lawfully in Recipient possession prior to receipt from the Disclosing Party;
		2. is in the public domain at the time of receipt from Provider;
		3. becomes part of the public domain through no fault of Recipient, its directors, officers or employees;
		4. is lawfully received by Recipient from a third party without an obligation of confidentiality to Provider; or
		5. is independently developed by Recipient without reference to or use of the Confidential Information; or
		6. is required to be disclosed subject to Applicable Law.
	3. The provisions of confidentiality and non-use shall survive the termination of this Agreement.
	4. This Agreement shall not restrict Recipient:
		1. from complying with a lawfully issued court order to produce or disclose Confidential Information, provided in each case Recipient shall timely inform the Provider and use all reasonable efforts to limit to the maximum extent possible, the disclosure and maintain the confidentiality of such Provider Confidential Information. In addition, Recipient shall permit Provider to attempt to prevent or limit such disclosure by appropriate legal means and;
		2. from publishing the Foreground Information in accordance with the terms of Section 8.
2. **Reporting and publications**
	1. Recipient provides the Provider with reports detailing the progress of the Project and the up to date Foreground Information on regular intervals to be agreed between the Parties prior to the start of the Project [optional: every @ months from the start of the Project]. Within thirty (30) days upon completion or early termination of the Project, Recipient shall provide Provider with a final report detailing up to date the Data and Foreground Information.
	2. Recipient shall inform the Provider immediately of any events that may hinder or obstruct the continuation of the Project pursuant to the terms of this Agreement and the Project Plan. Without prejudice to each Party’s rights and obligations under this Agreement, the Parties shall use reasonable efforts to agree on any measures to be undertaken to prevent or solve any such issues.
	3. Incidental Findings will be reported within [insert term] by Recipient to Provider. It is the responsibility of Provider to handle such Incidental Findings in accordance with its internal policies and Applicable Law.
	4. The Recipient acknowledges the importance of dissemination of the Foreground Information and agrees such Foreground Information (including the methods, knowledge and any Background Information that are necessary to include in any publication of the Foreground Information or necessary for other scientists to verify the knowledge contained therein) will be published in accordance with this Section 8.
	5. The Recipient shall submit to Provider a current draft of any intended publication at least thirty (30) days - or at least ten (10) working days in case of an abstract - before disclosure (the “Review Period”).
	6. Provider will inform the Recipient within the Review Period whether the publication:
		1. contains information that may be subject to a patent application. Recipient shall allow a delay of 60 days to safeguard any IPR in accordance with Section 9 hereof; and/or
		2. contains Confidential Information of the Provider that in the opinion of Provider has to be held confidential. Recipient shall remove any such information indicated by Provider from the publication at Provider’s request. If the Provider requests the removal of Confidential Information, the Provider agrees to allow the use of sufficient information regarding the identity and properties of the Material to enable the complete and accurate publication of the research results.
	7. Recipient shall take appropriate measures so as to ensure that any publication by Recipient, in whatever medium, of either Foreground Information as well as any deposition of any Samples required as part of a publication, shall be such so as not to allow any identification of the Subjects, whether by linking of such publication to public databases or otherwise.
	8. If Recipient has not published the Foreground Information within (twelve) 12 months after finalization of the Project, Provider is entitled to publish the Foreground Information. The provisions of Sections 8.5 and 8.6 apply to Provider vice versa.
	9. Recipient agrees that Provider may publish at any time after publication subject to this Section 8, on Provider’s website:
		1. general information about the analysis to the public;
		2. summary of the Foreground Information to registered users of the Provider website; and
		3. anonymous Subject-specific data to registered users of the Provider website.
	10. Recipient agrees to acknowledge Provider as the source of the Samples in any publication or other public disclosures related to the use of the Samples.

* 1. None of the Parties shall mention or otherwise use the name, trademark, trade name or logo of the other Party in any publication, press release or promotional material with respect to the Project without the prior written approval of such Party whose name, trademark, trade name or logo is projected to be used.
1. **Ownership IPR**
	1. Recipient acknowledges and agrees that the Samples are made available to the Recipient as a service to the research community and that Provider is the authorised custodian of the Samples. Provider shall be free, in its sole discretion, to distribute Samples of a similar or the same type as the Samples, to third parties at its election and to use the same for its own purposes, even if such biological human samples originate from the same Subjects as those whose Samples are made available under this Agreement.
	2. If the use of the Samples pursuant to this Agreement result in an invention or substance which may be commercially useful, Recipient will promptly notify the invention or substance to the Recipient’s patentadministrator and notify the Provider, as well as the role, if any, of any Provider’s employee in creating the invention or substance.

Any application for patent protection or protection under other IPR of such an invention or substance by Recipient shall be subject to the prohibitions and/or restrictions of the Informed Consent of Subject, which Provider shall make known to Recipient.

* 1. The Recipient shall be the owner of any Foreground Information to the extent these result from the Permitted Use. Recipient shall be entitled to use such Foreground Information as it deems appropriate, without further compensation to Provider. Recipient herewith grants to Provider and the INCbase Consortium members, and Provider and INCbase Consortium Members herewith accept, a worldwide non-exclusive, royalty-free, irrevocable license with respect to any Foreground Information for further research, patient care and educational purposes.
	2. To the extent Recipient and the Provider and other members of the INCbase Consortium have each contributed to the Foreground Information they shall jointly own such Foreground Information (“Joint Foreground Information”). With respect to Joint Foreground Information, the Parties shall negotiate in good faith additional terms and conditions for at least each Party’s and INCbase share of ownership to the Joint Foreground Information, the costs related to IPR protective measures, revenues, user rights and reporting. When the Parties and the INCbase Consortium cannot agree on such additional terms and conditions within nine (9) months from the expiration or termination date of this Agreement, each Party and the members of the INCbase Consortium are hereby granted a non-exclusive, worldwide, royalty-free, irrevocable licence to use the Joint Foreground Information for further research and educational purposes, with the right to grant non-exclusive sub-licences and without the need to inform the other Party.
	3. If Foreground Information is of potential commercial value, Recipient shall notify Provider forthwith in writing and Recipient shall use commercially reasonable efforts to further develop and exploit such Foreground Information. In the event Recipient is unable or unwilling to further develop and exploit the Foreground Information [add tailor made strategy].
	4. Any Foreground Information and/or data generated in violation with the Permitted Use by or on behalf of Recipient or as a result of unauthorized use or transfer by or on behalf of Recipient, shall be the sole property of the Provider and as the case may be the INCbase Consortium.
	5. Except as expressly set forth in this Agreement, nothing herein shall be deemed to grant to either Provider or Recipient or any member of the INCbase Consortium any rights under the other Party’s or the INCbase Consortium members’ Background Information.
1. **No Warranties**
	1. Any Samples provided pursuant to this Agreement are understood to be of human origin and may have hazardous properties.
	2. Both Parties acknowledge and agree that the Samples are made available with no warranties, express or implied, and Provider expressly disclaims any warranty of merchantability, fitness for a particular purpose, non-infringement of the use of the Samples pursuant to this Agreement of any third party rights, or that the Samples will not degrade in Recipient’s safe keeping.
	3. In respect of any other information or data supplied by one Party to the other in relation to this Agreement, the provider Party shall be under no obligation or liability other than as expressly stated herein and no warranty condition or representation of any kind is made, given or to be implied as to the sufficiency, accuracy or fitness for a particular purpose of such information or materials, or the absence of any infringement of any proprietary rights or third parties, by the use of such information.
2. **Indemnification**
	1. Unless claims, losses, liabilities and damages result from Provider’s wilful misconduct or gross negligence, Provider shall not be liable for any loss, claim, damage or liability, of whatsoever kind or nature, which may arise from or in connection with this Agreement, or the use, handling or storage of the Samples, including without limitation, any loss, claim, damage or liability which is the result of a contamination on the Samples, including but not limited to bacteria or viruses, that could possibly be harmful to those using the Samples by Recipient.
	2. If the Recipient will have part of the Project performed by a third party or give access to or transfers any Samples to a third party as permitted pursuant to Section 16 of this Agreement, Recipient shall remain responsible and liable to Provider for losses resulting from such third party’s use of the Samples as if such third party were the Recipient. Furthermore, a Party having part of its obligations under this Agreement performed by a third party, shall remain personally responsible for these obligations to the other Party.
3. **Payment**
	1. In addition to any payment agreed between Recipient and the INCbase Consortium, the Recipient shall pay to the Provider the compensation for the collection, maintenance and for making available the Samples in accordance with the budget and payment attached to this agreement as Attachment C, upon receipt of duly specified invoices from the Provider. Each invoice shall show VAT, if applicable, separately, in compliance to EU Council Directive 2001/115/EC. Under no circumstance shall any such payment or all payments collectively be construed as compensation for a transfer of any proprietary interest in either the Samples from the Provider or the Subject to Recipient or any third party.
4. **Term and termination**
	1. This Agreement will be effective upon final signature of this Agreement. This Agreement terminates on the earliest of the following dates: (a) on completion of the Project Plan and delivery of the final written reports pursuant to Section 8.1, or (b) on thirty (30) days written notice by either Party to the other.
	2. Either Party is entitled to terminate this Agreement or suspend its obligations with immediate effect in the event of the following:
		1. if approval from the relevant Review Committee(s) cannot be obtained or approval is permanently revoked;
		2. any material breach or failure to comply with any of the terms or conditions of this Agreement or Project Plan by one Party, which breach or failure, if capable of remedy, is not remedied within thirty (30) days after notice from the aggrieved Party demanding such remedy;
		3. if the other Party is unable to pay its debts, as they fall due, becomes insolvent or bankrupt or enters into any arrangements for the protection of its creditors or goes into liquidation;
		4. an encumbrancer takes possession or a receiver is appointed over any of the property or assets of that other Party;
		5. the other Party makes any voluntary arrangement with its creditors or becomes subject to an administration order that other Party goes into liquidation (except for the purpose of an amalgamation, reconstruction or other reorganization and in such manner that the entity resulting from the reorganization effectively agrees to be bound by or to assume the obligations imposed on that other under this Agreement);
		6. the other Party ceases, or threatens to cease, to carry on research or business; or
		7. if the approval for the Project is withdrawn by the INCbase Consortium.
	3. Any waiver by either Party of a breach of any provision of this Agreement shall not be considered as a waiver of any subsequent breach of the same or any other provision.
5. **Effect of Termination**
	1. Upon expiration or receipt of notification of early termination of the Agreement the Recipient shall:
		1. immediately cease and refrain from using the Samples;
		2. provide the final report as provided in Section 8.1; and
		3. promptly return or destroy of all used and unused Samples as instructed by Provider. As applicable, proof of destruction must be provided to Provider. Notwithstanding the foregoing, Recipient may request to retain certain Samples to the extent needed for validation purposes. Provider will not unreasonable withhold its approval to such request.
	2. Upon the termination or expiration of this Agreement or upon a Party’s earlier request, the Recipient Party shall promptly return to the Disclosing Party all Confidential Information from the Disclosing Party, provided that each Recipient Party shall have the right to retain a copy of the Disclosing Party’s Confidential Information in a secure location for purposes of identifying the Recipient Party’s obligations under the confidentiality provisions of Section 7.
	3. The rights to terminate this Agreement given by this section shall not prejudice any other right or remedy of either Party in respect of the breach concerned (in any) or any other breach. Upon the termination of this Agreement for any reason, subject as otherwise provided in this Agreement and to any rights or obligations that have accrued prior to termination, neither Party shall have any further obligation to the other under this Agreement.
	4. Sections [to be adjusted prior to completion of the Agreement] of this Agreement shall survive the expiration or termination of this Agreement and remain in full force and effect to the extent necessary to the intended preservation of such rights and obligations.
6. **Entire agreement**
	1. This Agreement contains the entire agreement between the Parties with respect to the subject matter hereof, and supersedes any prior agreements, negotiations or representations between the Parties with respect to the subject matter hereof, whether written or oral.
	2. This Agreement may be modified only by a subsequent written agreement signed by the Parties and approved by the relevant Review Board if appropriate. If any provision of this Agreement is held to be unenforceable, the remaining provisions shall continue unaffected.
7. **Assignment**
	1. Neither Party shall assign or sub-contract any of its rights or obligations pursuant to this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. Any third parties thus engaged by either Party in the performance of the Project shall be listed in Attachment D to this Agreement, provided they have assumed in writing all obligations of Recipient under this Agreement towards Provider and Subjects, as appropriate.
8. **Force Majeure**
	1. If either Party is affected by failure or delay due to natural disasters, war, acts of terrorism or any other cause beyond the reasonable control of a Party (“Force Majeure”), it shall promptly notify the other Party in writing within forty-eight (48) hours of the affected Party first having notice of the event and such notice shall as far as practicable state the nature and extent of the circumstances in question.
	2. Notwithstanding any other provision of this Agreement, neither Party shall be deemed to be in breach of this Agreement, or otherwise be liable to the other, for any delay in performance or the non-performance of any of its obligations under the Agreement, to the extent that the delay or non-performance is due to any Force Majeure of which it has notified the other Party, and the time for performance of that obligation shall be extended accordingly.
9. **Notices**
	1. Any notice required or permitted by the terms of this Agreement will be given by registered mail, prepaid and properly addressed or delivered by hand or by other recognized express carrier to Recipient or Provider at their respective addresses first given above or at such other address as either Party hereto may designate by notice pursuant hereto. If mailed, any such notice will be deemed to have been given when received; and delivered by hand when received.
	2. All communications from Provider to Recipient concerning this Agreement will be sent to:

[insert full address]

[attn.: @@@]

[e-mail: @@@]

[fax: @@@]

* 1. All communications from Recipient to Provider concerning this Agreement will be sent to:

[insert full address]

[attn.: @@@]

[e-mail: @@@]

[fax: @@@]

* 1. This Agreement is not assignable, whether by operation of law or otherwise, without the prior written consent of the coordinating UMC attached to Project Plan.

1. **Law changes, Governing Law and Venue**
	1. Provider shall advise and consult with Recipient on any changes in Provider’s national law, the status of Provider or in Provider’s policies, that may affect Recipient’s use of the Samples, or Recipients rights and obligations under this Agreement.
	2. This Agreement shall be governed by and enforced in accordance with the laws of the Netherlands.
	3. Any dispute arising from or related to this Agreement shall be finally settled by binding arbitration, conducted in accordance with the Rules of Arbitration of the Netherlands Arbitration Institute established in Rotterdam, The Netherlands by three (3) independent, neutral arbitrators appointed in accordance with said rules[[2]](#footnote-3). The place of arbitration shall be [insert city in the Netherlands]. If the Parties are not Dutch Parties, the arbitral procedure shall be conducted in the English language.
	4. The Parties agree that the final award of the Court of Arbitration shall be the sole, exclusive and binding remedy between them. Consolidation of the arbitral proceedings with other arbitral proceedings pending in the Netherlands, as provided in art. 1046 of the Netherlands “*Code of Civil Procedure*” is excluded. The award may be entered in a court of competent jurisdiction for a judicial recognition of the decision and an order of enforcement.
2. **Attachments**
	1. At the Effective Date, the following attachments are part of the Agreement:

 Attachment A : Project Plan (including Letter of Approval of INCbase SC)

 Attachment B : Identification of Samples and recipient persons

 Attachment C : Budget and Payment Schedule

 Attachment D : List of third parties involved in the Project

*Signatures on the next page*

In witness whereof, duly authorized representatives of the parties have signed this Agreement in two-fold, for:

|  |  |  |  |
| --- | --- | --- | --- |
| PROVIDER |  | RECIPIENT |  |
| Signature: |  | Signature: |  |
| Name: |  | Name: |  |
| Title: |  | Title: |  |
| Date: |  | Date: |  |
|  |  |  |  |
| Seen and acknowledged by**Provider Scientist** | Seen and acknowledged by Recipient scientist |
| Signature: |  | Signature: |  |
| Name: |  | Name: |  |
| Title: |  | Title: |  |
| Date: |  | Date: |  |
|  |  |  |  |

**Addendum #1**

**INCbase**

**Data Registry and Biomaterial Policy**

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## 1. Introduction and Scope

**Donor E-mail addresses**

A new feature will be added to the Registry whereby the Donor’s E-mail address will be centrally registered. The E-mail address will be used to automated distribution of questionnaires through the INCbase Registry software. As E-mail addresses are identifiable Personal Data, the INCbase Data Registry and Biomaterial Policy requires to be amended.

**Data Protection**

Each Donor consents for the Processing of its E-mail address and receiving the questionnaires as part of the informed consent to participate in the INCbase Registry. The E-mail addresses will be stored separately from the pseudonymised Data, but are linked to the pseudonym of the Donor. The Participating Member will have access to the general INCbase Registry interface. Each Participating Member has access to the E-mail addresses of its own Donors only. Participating Members will not have access to E-mail addresses from Donors of other Participating Members.

The Donor will receive an E-mail with a link to the questionnaire. The completed questionnaire bearing the Donor’s pseudonym is considered Data as defined in this INCbase Data Registry and Biomaterial Policy.

## 2. Additional Definitions

In this INCbase Data Registry and Biomaterial Policy the following terms have the meanings ascribed to them below:

1. E-mail: the automated messages sent to the E-mail Addresses and containing of a link to the Questionnaires.
2. E-mail Address: the E-mail address of each Donor that is stored in the E-mail Database. E-mail Addresses are identifiable personal data of the Donors and are not considered Data.
3. E-mail Database: the separate (part of the) INCbase Registry database, where the E-mail Addresses are stored.
4. Questionnaire: each questionnaire sent to the E-mail Address of the Donor. Completed Questionnaires are considered Data.

## 3. Processing of E-mail Addresses

1. Each Participating Member shall transfer the E-mail Address of Donors that consented to receive the Questionnaires, into the E-mail Database. The Participating Member shall enter the E-mail Address accompanied by the Donor’s INCbase Registry pseudonym. Consent shall be obtained in accordance with applicable national law of the country of residence of the Donor.
2. It is the responsibility and liability of each Participating Member transferring E-mail Addresses into the E-mail Database, to ensure such transfer is in compliance with its national law, including but not limited to privacy laws and that the E-mail Address can be used for the purposes set forth in **Section 4**.
3. To ensure the lawful processing of the E-mail Addresses as described herein, each Participating Member shall inform the Steering Committee of specific obligations following from its national mandatory law, that may affect the processing or use of the E-mail Addresses in relation to the INCbase Registry.
4. Each Participating Member shall ensure that the E-mail Addresses of Donors that did not consent to the Processing of their E-mail Addresses, will not be entered into the E-mail Database. In the event a Donor withdraws its consent to participate in the INCbase Registry or to receive Questionnaires, the respective Participating Member shall remove the E-mail Address of the Donor from the E-mail Database.
5. The E-mail Address of the Donor will be used exclusively for the purposes outlined in **Section 4** hereof.
6. The Coordinating Member, centrally managing the INCbase Registry, shall ensure the same security and safety level as for the INCbase Data Registry.
7. Each Participating Member may access the E-mail Database through its Registry log-in account. Each Participating Member shall have exclusive access to the E-mail Addresses of its own Donors.

## 4. Questionnaires

1. The Steering Committee will determine the content of the Questionnaires and the frequency the Questionnaires need to be completed.
2. E-mails will be sent as programmed in the E-mail Database e-mail automation software. Each Participating Member shall have the right to use the E-mail addresses of its Donors to sent the Donors additional questionnaires.
3. The Donors will receive an E-mail with a link to the Questionnaire. Once completed, the Questionnaire will be added to the Data of the Donor in the INCbase Registry and further Processed in accordance with the terms and conditions set forth in the INCbase Data Registry and Biomaterial Policy.

## 5. Privacy

1. Coordinating Member shall be responsible for hosting the E-mail Database in the same manner as the INCbase Registry Data database Coordinating Member shall in this respect be considered a data Processor on behalf of the Participating Members.
2. Participating Members shall ensure that the privacy of the Donors and the confidentiality of E-mail Addresses of their Donors are protected in accordance with the statutory requirements applicable in their own country and the policies of the institution of which the Donor is a patient.
3. Each Participating Member is considered the Controller of the E-mail Addresses it entered into the E-mail Database and shall fulfil all obligations of Controller under applicable privacy law.

## 6. Miscellaneous

This Addendum forms an integral part of the INCbase Data Registry and Biomaterial Policy.

1. The processor at the starting date of the INCbase Registry is [name and address processor]. The provisions relating to the processor in this matrix shall apply to all successors of such processor. [↑](#footnote-ref-2)
2. <http://www.nai-nl.org> [↑](#footnote-ref-3)