



UNIVERSITÀ DEGLI STUDI DI TORINO
DIPARTIMENTO DI SCIENZE MEDICHE

DATA TRANSFER AGREEMENT

The Undersigned,

Department of Medical Sciences of the University of Turin, (hereinafter referred to as **“Provider”**), having its registered offices located at corso Dogliotti, 14 – 10126, Torino, represented by Professor Elisabetta Bugianesi, Head of the Department, in her role as legal representative

and

Department of YYYY (hereinafter referred to as **YYY** or **“Recipient”**), having its registered offices located at xxxxxxxxx, represented by wwwwww, Head of the Department, in his/her role as legal representative,

hereinafter jointly referred to as **“Parties”** and individually as **“Party”**;

PURPOSE:

This Agreement establishes the terms and conditions under which Provider and Recipient will share already available data (listed in Annex A) from the NINFEA project, and how the parties will store, maintain, use and ensure confidentiality of this data.

WHEREAS

- a) Provider and Recipient are entities, having scientific research among their institutional purposes;
- b) Provider has collected certain Data within the NINFEA project, started in 2005 and still ongoing;
- c) Provider is willing, subject to the terms and conditions of this Agreement, to provide the Data (see Annex A) to Recipient for the Project called XXXXXX (Annex B);
- d) The Parties have agreed to co-operate with each other in relation to the share and use of the data in accordance with the terms and conditions of this Agreement.

Now, therefore, in consideration of their mutual promises to each other, hereinafter stated, the Parties agree as follows:

I. Definitions

- 1. **AGREEMENT:** This Data Transfer Agreement.
- 2. **APPLICABLE LAW AND REGULATIONS:** The European law and regulation applicable to processing (e.g. collecting, storing, processing, transfer, and use) of Personal Data, including the Directive 95/46/EC (on the protection of individuals with



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- regard to the processing of personal data and on the free movement of such data) and any implementation thereof in national law, and any data protection law applicable in the country of Provider and Recipient (incl. the EU General Data Protection Regulation (EU) 2016/679 as of May 25th, 2018).
3. **CONFIDENTIAL INFORMATION:** any proprietary information, know-how, data, or procedure related to the Data and disclosed by Provider to Recipient pursuant to its rights or obligation under this Agreement, in oral or a written form, or recorded or stored by electronic, magnetic, electromagnetic or other form, process or otherwise in a machine-readable form or translated from the original language.
 4. **DATA:** the anonymized data being transferred under this Agreement as specified in Schedule 1 to this Agreement.
 5. **EFFECTIVE DATE:** The date of last signing of this Agreement.
 6. **INFORMED CONSENT:** The written, signed and dated consent from the Subject or its legal representative, based on sufficient and understandable information, covering the collection, storage and use of its Personal Data.
 7. **INVESTIGATOR(S):** The employees/investigator(s) of Recipient that shall have access to the Data under this Agreement.
 8. **PERMITTED USE:** The permitted non-commercial and academic use of the Data as specified in Annex B.
 9. **PERSONAL DATA:** 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.
 10. **PROJECT:** The specific project specified in Annex B of this Agreement for which the DATA will be used.
 11. **PROVIDER:** The Party that has collected the Data
 12. **RECIPIENT:** The Party wishing to access the Data.
 13. **SUBJECT:** The individual from whom the Personal Data originated or to whom the Personal Data is related to.
 14. **TERRITORY:** Means the country of the Recipient

II. Terms and Conditions of this Agreement:

1. The Parties agree to abide by and comply with all Applicable Laws and Regulations.
2. Provider represents that, to the extent applicable, it has obtained the proper Informed Consent from each Subject in accordance with the Applicable Laws and Regulations, which allows for the use of the Data for the Permitted Use.
3. The Data is proprietary to Provider and this Agreement does not restrict Provider in any way to use the Data and/or to make the Data available to third parties or to publish any document directly or indirectly relating to the Data. Recipient shall solely use the Data for the purposes indicated therein and as further specified in the Permitted Use and in the Annex B. Recipient is granted for the duration of the Agreement a non-exclusive,



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non-transferable, and non-sublicensable license to use the Data in the Territory for the Permitted Use only. Recipient will retain the Data in a secure location on its premises and will ensure that suitable systems are in place for the tracking of Data while in its possession. Recipient agrees not to give access to or transfer the Data, in whole or part, to any third party or outside the Territory without Provider's prior written approval. Only those Investigators as set out in Annex B may have access to the Data. No payments shall be due, unless otherwise agreed in Annex B.

4. Recipient shall treat all Data and Confidential Information as confidential. Recipient will provide appropriate administrative, technical and physical safeguards to ensure the confidentiality and security of Data and to prevent unauthorized use or access to it. Excluded from this obligation of confidentiality shall be any Data and Confidential Information of which Recipient can reasonably demonstrate that it (a) was previously known to Recipient, or (b) is, and/or becomes, publicly available during said five (5) year period through no fault of Recipient, or (c) is independently and lawfully developed by Recipient. This obligation of confidentiality shall not apply to any disclosure required by law, provided that Recipient shall notify Provider of any disclosure required by law in sufficient time so that Provider may contest such requirement, if the Provider chooses. However, the foregoing exceptions shall not apply to: (a) Data and Confidential Information contained within more general information that may fall within one or more of the exceptions, or (b) any combination of features or items of Data and Confidential Information where one or more of the relevant individual features or items (but not the combination itself) may fall within one or more of the exceptions.
5. Recipient acknowledges that Subjects – and/or their legal representatives on their behalf – may withdraw or change their initial Informed Consent. Provider shall insofar necessary promptly notify Recipient of any withdrawal of or changes in the Informed Consent of a Subject, which may affect the use of such Subject's Data under this Agreement. Recipient shall follow the instructions of Provider in the handling and/or disposal of the respective Data.
6. Recipient shall inform Provider of the progress of the Project and the results arising from the Project. The results shall be considered joint property of Provider and Recipient, and both Parties shall have the right, free of charge, to use the results of the Project (not the Data) for further research and education purposes; provided, however, that for



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commercial use, both Parties shall first consult each other and make appropriate arrangements in writing.

7. Recipient will provide any material for publication for review to Provider at least forty-five (45) calendar days prior to submission for publication, public dissemination or review by a publication committee. If Provider does not object within thirty (30) calendar days after receipt, Recipient will be free to proceed with the intended publication of research results without further delay. During the forty-five (45) day period for review, Provider shall be entitled to:
 - I. make a reasoned request to Recipient to delay the publication for an additional period of forty-five (45) days (following the forty-five (45) day period for review) in order to enable Provider to take steps to protect its proprietary information and/or intellectual property rights and know-how, and Recipient shall not unreasonably withhold its consent to such a request; and
 - II. cause Recipient to remove from the projected publication any confidential information from Provider that is not Recipient's own research resulting from the Project. Recipient will adapt the proposed publication in such a way that it will not publish the confidential information that is indicated by Provider. Recipient will only have the right to publish the adapted proposed publication after the written consent from Provider.
8. Recipient will appropriately acknowledge the NINFEA project as part of Provider's contribution of the Data and include, if appropriate and agreed, co-authorships for any other contribution to any publication reporting the results of the Project. All publications reporting the results of the Project will be made in accordance with internationally recognized scientific and ethical standards concerning publications and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, established by the International Committee of Medical Journal Editors. Specific co-authorship arrangements may be agreed upon between the Parties. In such cases, the Parties shall document these arrangements in a written annex to this Agreement. This annex shall outline the respective roles, contributions, authorship order, rights, and responsibilities of each Party. The annex shall form an integral part of this Agreement and shall prevail in case of any conflict with the main provisions of this Agreement concerning co-authorship.



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9. Provider shall transfer only anonymous Data and as such in no event can lead to the identification of an identifiable natural person. Hence, the Data is not considered Personal Data. Recipient shall refrain from tracing and/or identifying any Subject and will not try to link the Data provided by Provider to other data held by different Recipients or by the same Recipient for different projects. 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 and inform Provider in writing of such identification.
10. Provider makes no representations and extends no warranties of any kind, either expressed or implied with respect to the Data, such as but not limited to any representation or warranty on accuracy, completeness, availability, accessibility, fitness for a particular purpose, or that the use of the Data will not infringe any rights of third parties. Provider shall not be liable for any liability or damages with respect to any claim by Recipient or any third party on account of, or arising from, this Agreement or the use of the Data. Recipient hereby agrees to indemnify and hold Provider, its personnel and its subsidiaries harmless from any loss, claim, damage, expense, or liability, which may arise from Recipient's use, storage and disposal of the Data, except to the extent such loss, claim, damage, expense or liability is the direct result of the Provider's gross negligence or willful misconduct. The Parties agree that to the maximum extent permitted by Applicable Laws and Regulations, in no event will any party (including its affiliates and subcontractors, and their respective directors, officers, and employees) be liable for any indirect, special, consequential, incidental, punitive or non-contractual damages (including without limitation damages for lost profits, loss of revenue and loss of business opportunities) arising out of or related to this Agreement.
11. Recipient will use all reasonable endeavours to ensure that the Data in its possession or under the control of Recipient shall, unless as agreed otherwise in writing, as soon as possible be returned or destroyed upon (i) the reasonable request of Provider; or (ii) on termination of this Agreement; or (iii) in the event that Recipient is in breach of any conditions of this Agreement. If Recipient is required to destroy the Data then it will ensure that this is done in compliance with all Applicable Laws and Regulations and will confirm in writing to Provider that the Data has been destroyed.



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12. This Agreement enters into force upon the Effective Date and shall remain into force until **DD/MM/YYYY**, when the Agreement and the license granted hereunder shall automatically terminate. Either Party is entitled to terminate this Agreement or suspend its obligations with immediate effect in the event of the following:

- I. any material breach of or failure to comply with any of the terms or conditions of this Agreement 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;
- II. the other Party ceases, or threatens to cease, to carry on research.

Upon termination or expiration of the Agreement Recipient shall:

- I. immediately cease and refrain from using the Data, and
- II. promptly delete all Data, to be confirmed in writing to Provider as soon as possible.

13. This Agreement contains the entire agreement between the Parties with respect to use of the Data, and supersedes any prior agreements, negotiations or representations between the Parties with respect to the subject matter hereof, whether written or oral. The annexes to this Agreement form an integral part of the Agreement. In case of conflict between the provisions of this Agreement and its Annexes where such deviation is not specifically permitted, the provisions of this Agreement shall prevail. This Agreement may be modified only by a subsequent written agreement mutually signed by both Parties. If any provision of this Agreement is held to be unenforceable, the remaining provisions shall continue unaffected.

14. This Agreement will be binding upon and inure to the benefit of the respective successors and assignees of the Parties hereto. However, Recipient may not assign this Agreement in whole or in part without the prior written consent of Provider.

15. 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 one (1) calendar month 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. 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



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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.

16. Both Parties acknowledge that the signatories to this Agreement are authorized representatives of each of the Parties and legally authorized to sign this Agreement.
17. Any notice required or permitted hereunder shall be in writing and shall be deemed effectively given upon delivery to the person indicated in this section, or the day after delivery to a recognized overnight courier, to the following addresses:

If to Provider:

UNIVERSITY OF TURIN

Department of Medical Sciences

Cancer Epidemiology Unit

Attn: Prof. Lorenzo Richiardi

Via Santena 7

10126 Turin, Italy

e-mail: lorenzo.richiardi@unito.it

with CC via e-mail: maja.popovic@unito.it

If to Recipient:

18. This Agreement shall be construed and governed exclusively in accordance with the laws of Italy and the European Union's Rights and Regulations. Any and all disputes arising from or in connection with this Agreement that cannot be settled amicably by and between the Parties hereto, shall be subject to the exclusive jurisdiction of the court of Turin, with an express waiver of any other jurisdiction to which they may be entitled.



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IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals, by their duly authorized legal representatives,

For **PROVIDER**

For **RECIPIENT**

Signature: _____

Signature: _____

Name: Professor Elisabetta Bugianesi

Name: _____

Position: Head of Department

Position: _____

Place: _____

Place: _____

Date: _____

Date: _____

Signature: _____

Name: Professor Lorenzo Richiardi

Position: PI of the NINFEA project

Place: _____

Date: _____

Read and acknowledged by Recipient's Principal Investigator(s), as specified in Annex B

Signature: _____

Name: _____

Position: _____

Place and date: _____



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Signature: _____

Name: _____

Position: _____

Place and date: _____

Signature: _____

Name: _____

Position: _____

Place and date: _____



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Annex A – Requested Data

List variables / questions from the NINFEA project indicating for each variable/question the source questionnaire.



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Annex B - Description of the Project under the Agreement

This Project-Specific Annex shall be completed per Project for administrative purposes and shall be subject to the terms and conditions of the Agreement.

Project title:

Project rationale and objectives:

Planned analyses: