**Data and Material Sharing Agreement**

**Collaborating Research Project**

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

a) Akershus University Hospital (Ahus), Sykehusveien 25, Po. Box 1000, 1478 Lørenskog, Norway (Provider)

and

b) <*Name of Institution and address*> (hereinafter NN)

This Agreement records the terms under which the Parties will share *fyll inn* (the Material and/or Data) as part of a collaborating Research Project <*Title*>, within the research group of NN (*fyll inn).*

Any Material and Data provided by Ahus under this Agreement is regulated in accordance to the Norwegian Health Research Act and by following approval:

* Ethical approval from Regional Committee for Medical Research Ethics, ref.no.: (*fyll inn*)

## **DEFINITIONS**

Project Results means all the results, information, ideas, methods, solutions, devices, materials, data etc. arising from the Research Project, irrespective of whether they are or can be protected by Intellectual property rights.

Background means all information, ideas, methods, solutions, devices, materials, data etc. necessary for the Research Project and generated outside the Research Project, irrespective of whether they are or can be protected by Intellectual property rights.

Intellectual property rights mean all protection forms of intellectual property rights including but not limited to patents applied for inventions and for other innovations that are part of the Project Results, utility models, trademarks, copyrights and confidential know-how.

Ownership comprises law of properties, patents, patent applications, inventions, copyrights and other Intellectual property rights.

User rights mean rights to use the Project Results in a Party's own research for non-commercial purpose, internal research and teaching purposes.

Confidential Information shall mean all information (including but not limited to any knowledge, trade secrets, scientific material, data, drawings, samples, specifications, devices, demonstrations, information concerning the structure, design and code of software, know-how and other materials of whatever description whether or not subject to or protected by copyright, patent, trademark, registered or unregistered or otherwise) disclosed or communicated in writing, orally or in electric form or that has otherwise become known to the Party in connection with this Research Project by above mentioned means.

## **CONDITIONS**

The Material and/or Data will be made available to the receiving Party as part of conducting the Research Project set forth under the following conditions:

The providing Party will arrange shipping of the Material, and will be responsible for the Material until it is delivered. Recipient Party will reimburse the providing Party for the shipping costs.

The receiving Party will hold the shared Material and/or Data on the terms of this Agreement and solely for the purpose of conducting the Research Project as described in attached protocol.

When personal data is to be transferred from the European Economic Area to a third country, an agreement stating the standard contractual clauses for transfer will also be signed, in accordance with the General Data Protection Regulation (GDPR, EU regulation 679/2016).

The Material and/or Data will be made available for the receiving Party without any direct personal identification to the human subjects such Material and/or Data have been derived from. The receiving Party must under no circumstances attempt to reidentify data subjects.

The Material and/or the Data derived from the Material, OR any other Clinical Data, may only be used under the receiving Party’s direct supervision and under suitable containment and protected conditions, and in compliance with Annex 1, applicable laws, regulations and necessary approvals.

Each Party is responsible for all handling and storage of said Material and Data as required by local regulations regarding management of sensitive information.

The receiving Party will not transfer the Material or Data to any other body, or permit its use within its own Institution other than within the collaborating research group, without (in each case) prior written consent from the providing Party. The Material and/or Data may not be used in activities subject to the provision of any rights to a commercial third party without prior written consent from the providing Party.

The receiving Party undertake that the Material is experimental in nature, and may have hazardous properties. The Parties makes no representations and give no warranties either express or implied in relation to it: for example, no warranties are given about quality or fitness for a particular purpose; or that the use of the Material will not infringe any intellectual property or other rights of third parties.

Except to the extent prohibited by law, the receiving Party assume all liability for damages which may arise from its own use, storage or disposal of the Material and Data. The Parties will not be liable to the other Party for any loss, claim or demand due to, or arising from the use of the Material or Data.

The liability of either Party for any breach of this Agreement, or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.

Upon completion of the Research Project or termination of this Agreement (whichever comes first), the receiving Party will return or destroy all Material/Data as instructed by the providing Party.

## **OWNERSHIP AND USER RIGHTS**

The providing Party retains the Ownership and all rights to the Material/Data provided to the receiving Party.

The Ownership to the Project Results shall belong to the Party who has created, invented or generated it. Project Results created or generated jointly by the Parties shall belong jointly to the parties, each with a share corresponding to their relative contribution to the Project Result.

The specifics concerning securing Intellectual property rights to jointly owned Project Results, the commercial purpose and the compensation shall be regulated in a separate agreement between the Parties. Ahus will involve its technology transfer office in such a process.

Unless otherwise agreed, the Parties may only use jointly owned Project Results for commercial purposes or grant licenses to third parties under the following conditions:

1. the other joint owner must give its prior written consent, which shall not be unreasonably withheld; and
2. fair and reasonable compensation must be provided to the other joint owner, to be negotiated in good faith.

Regardless of ownership, each Party shall have a royalty-free non-exclusive User Right to the Project Results for non-commercial research and teaching purposes.

The Ownership of the Background shall not be affected by this Agreement. In case that the other Party's Background is needed for exploitation of the Project Results, the Parties may agree on conditions for granting User Rights. A Party shall not be obliged to grant rights to its Background to the other Party.

## **CONFIDENTIALITY**

Each Party shall keep Confidential Information disclosed or communicated to it, directly or indirectly, from the other Party in strict confidence, and shall not use Confidential Information for any other purpose than specially stipulated in this Agreement. The obligation for confidentiality shall not apply if the Confidential Informati­on:

1. was at the time of receipt published or otherwise generally available to the public;
2. has after receipt by the receiving Party been published or become generally available to the public otherwise than through any act or omission on the part of the receiving Party;
3. was already in the possession of the receiving Party at the time of receipt without any restriction on disclosure;
4. was rightfully acquired from a third party without any undertaking of confidentiality;
5. was developed independently by the receiving Party without any connection to the collaboration; or
6. is required to be disclosed by applicable law or court order.

## **PUBLICATION**

The Parties shall secure openness regarding the Research Project. All research results from the study shall be sought published, regardless of whether they are favourable or unfavourable to a research hypothesis or theory. The Parties may agree upon making a plan for publication based upon the criteria set by the latest version of the Vancouver convention on co-authorship on scientific publications.

The parties will mainly seek to publish Project Results jointly.

Unless stated otherwise, the parties have the right to publish results from data collected within their institution unless such a publication will disclose confidential information, trade secrets or in other ways weaken the potential presentation of the study significantly compared to publication of the Project Results in a broader context. Each Party shall notify the other about planned publications from research utilizing the Material and/or Data, and the other Party shall be given the opportunity to suggest changes and scope of the publication in favour of a broader and more representative presentation of the results. A Party may also request removal of trade secrets or other confidential information.

Each Party can request postponement of publication in order to implement the necessary measures to protect Intellectual Property Rights. Such postponement shall not exceed 90 days without written approval from the other Party.

## **DURATION AND TERMINATION**

This Agreement shall commence on the date of the last signature below and will continue for the duration of the Research Project.

Each party may terminate this Agreement for any reason upon 3 months’ written notification to the other Party, or within 30 days if the other Party is in material breach or not capable of fulfilling its obligations under this Agreement.

Upon completion of the Research Project or earlier termination the Parties will discontinue all use of the Material and Data, and upon request of the other Party, return or destroy any Material or Data unless otherwise has been agreed in writing between the Parties.

Following expiry or termination, sections 3, 4 and 5 will continue to be valid between the parties.

## **DISPUTES AND NEGOTIATIONS**

The Parties shall attempt, in good faith, to resolve through negotiations any controversy, claim, or dispute arising out of this Agreement. In the event that negotiations are not successful, the controversy, claim, or dispute shall be submitted to third party mediation upon terms reasonably acceptable to the parties. If mediation of the dispute is not pursued or is not successful, the parties may pursue any and all remedies available to them at law or equity.

## **ENTIRE CONTRACT AND AMENDMENTS**

This Agreement constitutes the entire agreement between the Parties in respect of the Research Project. Any amendments and changes to this Agreement shall be valid only if made in writing and signed by an authorised signatory of each Party.

This Agreement has been executed in two (2) originals, one for each Party.

## **SIGNATURES**

|  |  |
| --- | --- |
| **<*Collaborating Institution*>** | ***Akershus University Hospital*** |
| Name: | Name: |
| Position: | Position: |
| Signature | Signature: |
| Date: | Date: |

**ANNEX 1:**

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| --- | --- |
| Project title: |  |
| Project leader (PI): |  |
| Material/Data specifications: |  |
| Analyses to be performed: |  |
| Reference to Ethical approval: |  |