

DATA TRANSFER AGREEMENT

between

**University of Bern
Institute of Social and Preventive Medicine, 3012 Bern
Switzerland**

(hereinafter referred to as "University")

and

(hereinafter referred to as "Partner")

Preamble

University participates in the EU FP7 funded research project "BESTCILIA" ("Project"). Among University's tasks in the Project is the preparation of a joint dataset for analysis out of different datasets collected by several partners from within or outside the Project, the evaluation and interpretation of certain epidemiological and clinical data. The Partner is willing to provide patient related data relevant for the Project ("Data") subject to the terms and conditions of this Agreement.

The parties thus agree as follows:

- 1) The Data shall remain the property of the Partner. University shall treat the Data confidential and not distribute the Data to third parties, except that University shall be allowed to transfer extracts of datasets to the partners contributing data within and outside of BESTCILIA according to Art. 5 below and upon consent of Partner. In the event Partner should decide to withdraw his consent to the use of his Data as described herein, it shall have the option to terminate this Agreement. University will then return and not further use the Data.
- 2) The Partner shall be responsible for ensuring that sent Data are strictly anonymized (as described in Exhibit B) and is provided in accordance with applicable national/local data protection laws.
- 3) The Partner shall adhere to safe data transfer procedures as will be defined by University (Exhibit B).
- 4) In the event University sees potential to scientifically publish findings derived from/related to the Data, University will provide to Partner a concept sheet for such publication. The Partner shall have the right to provide input to the concept sheet and the planned publication overall. Once the parties agree on the modalities regarding such publication they shall conclude a separate publication agreement along the lines of the template attached hereto as Exhibit A. For clarity, the Partner shall have no obligation to enter into a publication agreement with University. If the Partner opposes to a publication pursuant to this Article, University will not use the Data for this specific publication.
- 5) Publications: For the firstline papers, essential for BESTCILIA, University will take the lead. Concept sheets on other topics ("Additional Papers") can be proposed by all partners

contributing data. All concept sheets have to be approved by all partners contributing data to the proposed paper under question.

Once the parties agree to publish, the following general publication rules shall apply:

- general authorship rules of the International Committee of Medical Journal Editors will be adhered to
- the first and last author will usually be from the institution which is responsible for the specific paper.
- whenever possible, all partners contributing data on a significant number of subjects will be offered a co-authorship. Depending on the topic of the publication, target journal and number of involved data providers, this general rule might need to be adapted for some publications.
- second and second last co-authorship will be offered to co-authors who have a major input in data analysis or writing, or who provided data on a very large number of subjects
- remaining co-authors will be listed alphabetically
- all partners contributing data shall be duly acknowledged

For Additional Papers, University will extract the appropriate anonymous dataset ("Dataset") and send it to the relevant partner ("Recipient"). Such transfer of data needs to be approved by the data provider(s) concerned. When possible (depending on funding), University can offer to perform the statistical analysis for the partner having proposed the publication. The funding necessary for analysis and writing of Additional Papers will be organized by the institution which is responsible for the specific paper. The Recipient agrees to use the Dataset only for the agreed publication and will otherwise warrant confidentiality of the Dataset and will destroy all copies of the Dataset in his possession within 3 months after this publication is accepted.

For University:

For Partner:

Bern, Date: _____

Place, Date: _____

Prof. Dr. Claudia Kuehni
Principal Investigator

Collaborator

Exhibit A: Template for Publication Agreement

Exhibit B: Anonymization of Data and safe Data transfer procedures

Exhibit A: Template for Publication Agreement

PUBLICATION AGREEMENT

between

**University of Bern
Institute of Social and Preventive Medicine,
3012 Bern, Switzerland**

(hereinafter referred to as "University")

and

(hereinafter referred to as "Partner" or in the event of several partners as "Partners", as the case may be)

Preamble

WHEREAS, University is partner in the EU FP7 funded research project "BESTCILIA". Among University's tasks in this project is the preparation of a joint dataset for analysis out of different datasets collected by several partners from within or outside the project, the evaluation and interpretation of certain epidemiological and clinical data;

WHEREAS, University and Partner(s) have concluded a Data Transfer Agreement on _____ [execution date] and Partner has provided data to University for evaluation within the BESTCILIA project ("Data");

WHEREAS, the University and Partner intend to publish certain findings based on the Data.

The parties thus agree as follows:

Article 1: Publication

- 1.1 The parties intend to jointly publish, based on a concept sheet and an analysis dataset provided by University, the following scientific findings _____ [working title] in _____ [Journal] ("Publication"). If the manuscript is rejected by the journal of choice, the choice of alternative journals will be made in discussion between University and all Partners.
- 1.2 As agreed in the Data Transfer Agreement, the following publication rules in accordance with the regulations of the International Committee of Medical Journal Editors shall apply:
 - the first and last author will be from the institution which is responsible for the specific paper.
 - all partners contributing significant numbers of datasets will be offered a co-authorship.
 - second and second last co-authorship will be offered to co-authors who had a major input in data analysis or writing, or who provided a very large number of datasets
 - remaining co-authors will be listed alphabetically
 - all partners contributing data shall be duly acknowledged

Thus, the parties now agree upon the following authorship for publication:

- First author: _____
- Last author: _____
- Second author: _____
- Second last author: _____
- Co-authors or contributing partners defined according to the criteria of the International Committee of Medical Journal Editors; from University and from Partner(s):

...

1.2 The planned timeline of the publication is as follows:

- dataset delivered from University to the partner responsible for this publication:

- results (tables) circulated by the responsible partner to all co-authors and data providers: _____
- first draft of the publication circulated by the responsible partner to all co-authors and data providers: _____
- final draft of the publication circulated by the responsible partner to all co-authors and data providers: _____
- latest possible date for submission of the publication to the target journal:

1.3 If these deadlines are not kept and the manuscript is not submitted to the target journal 2 years after receipt of the data at the very latest, the responsible partner loses its leadership and the topic is again open for other data providers (upon circulation and acceptance of a concept sheet).

Article 2: Miscellaneous

No agreements altering or supplementing the terms may be made except by a written document signed by the duly authorized representatives of the parties.

For University:

For Partner:

Bern, Date: _____

Place, Date: _____

Prof. Dr. Claudia Kuehni
Principal Investigator

Collaborator

Exhibit B: Anonymization of Data and safe Data transfer procedures

Anonymization of Data

Before uploading the Data, make sure it is anonymous:

1. Assign each patient a unique patient identification code. Use a 3 letter abbreviation for your site (INA), followed by an ascending unique 3 digit number (e.g. INA001 to INA420).
2. You should keep a list of the codes corresponding to each patient, in case you need to get further detail out of the patient charts later. This list is for your own internal use, never send it to us.
3. Erase all names of your patients in the dataset.
4. Erase all contact details (address, phone numbers, e-mail).
5. Erase all other identifying data (e.g. social security number, health insurance number, official patient number in the hospital).
6. Replace the day of the date of birth by 15.

Safe data transfer procedures

(This is a draft. It will be personalized in the final version).

1. Archive and encrypt your dataset file using WinZip with 256 Bit AES. You are free to choose the file type for your dataset (Access database, Stata files, Excel sheets, etc.)
2. Upload the zipped Data on our sharepoint server:

Link to the website:

https://sharepoint.ispm.unibe.ch/sites/BESTCILIA_WP1

(Every site will get an own secured folder, and an own link.)

Choose the option "Windows Authentication"

User name: *(we will provide you with your personal username)*

Password: ****** (we will provide you with your personal password)*

Once you get to the welcome page, you can upload your encrypted zipped dataset by clicking on "Add a document".

3. Inform us by e-mail (pcd@ispm.unibe.ch: Claudia Kuehni, Myrofora Goutaki and Elisabeth Maurer) that you have uploaded your data.
4. Send us a second e-mail containing, in the body of the message, the password you used for WinZip encryption. Do not include any other text. Put your site name in the subject line; do not use a text like "password for...".