IMPORTANT: All principal investigators and their research team/collaborators must read these guidelines prior to starting the study. The PIs must digitally sign the last page to confirm their agreement on behalf of their research team and centre/institution.

Data Storage, Access, Ownership And Transfer Guidelines

Table of Contents

Guidelines 2
- Data Storage 2
- Rights To Use Data 2
- Data Transfer Agreement 2
- Data Ownership 3
- Frequently Asked Questions 3

Data Transfer Agreement 4

Guidelines

Data Storage

All uCARE studies will be collected and stored centrally with the help of a web-based data management system (DMS). Only authorized users with a valid username and password will have access to the study of interest and will be able to enter data into this system. Should a principal investigator assign the task to any member of his team, it is his responsibility to contact uCARE so that we can provide this person their own username and password to access the system before using the DMS for entering data. For audit and monitoring purposes, each user must have their own username and password to use the system. For example, the PI cannot share his login information to be used by any member of his team in order to enter the data for a patient. The PI is responsible for the quality, accuracy and security of their site's data and to adhere by the guidelines on data access, transfer and use of uCARE data.

Formal supervision, usually the responsibility of the principal investigator, should be provided for all research projects: this must include quality control, and the frequent review and long-term retention (may be up to 15 years) of all records and primary outputs.

uCARE will conduct regular monitoring of the data from the sites in order to ensure the data collected and stored in the DMS is secure and is of the highest quality.

Rights To Use Data

1. Except as expressly permitted under these principles, and to the maximum extent permitted by applicable law, a uCARE member shall not, and shall not permit any third party to attempt to copy, modify, duplicate, create derivative works from, frame, republish, download, display, transmit or distribute all or any portion of the data or the DMS.
2. Each uCARE member must comply with any reasonable security measures implemented by the uCARE committee for access to the data or the DMS.
3. Each uCARE member acknowledges and agrees that it will not access or use the data or the DMS (in whole or in part) for commercial purposes without the prior approval of the uCARE Council.

Data Transfer Agreement

A data transfer agreement will be provided between each principal investigator and uCARE. This agreement defines the obligations and rights of each involved party regarding the use of data. A Data Transfer Agreement will be sent to you separately.

Data Ownership

To the extent permitted by law, the intellectual property rights and ownership of all the patient data collected and managed in the data managements system will remain with uCARE. Unless otherwise required by law, or allowed by this agreement, a uCARE member may not, at any time, claim any legal interest in, intellectual property rights over, or ownership of the data or patient data. With respect to publication rights, please refer to the **uCARE Authorship and Publication Guidelines**.

Each uCARE project will identify and follow the appropriate security requirements for all databases and data stored under the approved uCARE project plans. This includes responsibility for maintaining the quality and security of the data, throughout the generation, collection, processing, storage, access, dissemination, and disposal of the data. The principal investigator and any member of his team who is conducting the uCARE study shares this responsibility by ensuring all data that is collected is an accurate reflection of the patient's medical record, and is of high quality.

Frequently Asked Questions

1. **Who will have the access to the data?**
   All contributors should have access to data from their country. The Research Office will provide regular updates (reports) to show the status of the study (including all centres) to all Council members and the research centres.

2. **Who can use the data for analysis and propose a certain study?**

   All members contributing data to a certain project can use the data for analysis. Members will have access to data from their country.

3. **How long is the access of the data?**
   Access to the data will be for a limited time.

4. **Is a uCARE centre responsible for updating their data previously attributed to uCARE research projects?**

   Yes, the centre is responsible for the updating and follow-up of the data.

5. **What if a uCARE member would like to propose a new study based on previously stored data in the DMS after the original project has been completed?**

   Since SIU (uCARE) is the owner of the data, the uCARE member who proposed this idea must request for the uCARE Council's approval alone, without getting the approval from each contributor of the data.

Data Transfer Agreement

uCARE represents a global collaboration between its member societies. Therefore, it is vital that a mutual and robust commitment is agreed upon in order to secure the ethical and scientific integrity of clinical research globally. This will facilitate the discovery and generation of high quality care for all patients. The purpose of this agreement is to ensure that all parties arrive at a mutual agreement regarding the use of data in order to prevent disagreements and avoid participation refusals arising from misconceptions.

The Data Transfer Agreement is made between the ‘‘Researcher’’ (and his institute participating in the study) and uCARE (‘‘Recipient’’). For the purposes of this Agreement, “Data” means the raw, non-aggregated data collected during the course of the Study. “Study Results” refers to the aggregated or summarized Study Data and conclusions about the Study, as would be included in a study report or publication. The Principal Investigator (PI) is free to publish or present the Study Results, subject to the provisions of the uCARE Authorship and Publication Guidelines, and upon submitting a publication request to the uCARE office.

The parties hereby agree as follows:

1. **Data.** The Data to be furnished by Researcher to Recipient consists of the items defined in and set forth in an Appendix 1 (attached ‘‘Study”. In this case, Study Protocol: uCARE-2018-001).

2. **Permitted uses.** Recipient will only use Data for the purpose(s) and project(s) specifically set forth in the Appendix (the ‘‘Study’’). However, it is acknowledged that the Data may be a resource for other scientific projects or uses. As such, the parties agree that the Recipient has the right to use and further distribute and/or transfer the Data to any third-party, provided that such use or transfer is made for a scientifically approved project or use as determined by Recipient, and is done in accordance with applicable laws, rules and regulations regarding the use, handling and transfer of the Data. A separate clinical study research agreement between the Recipient (uCARE) and the sponsor will be developed for each study. The sponsor may use copies of the data and information delivered under contract for research and evaluation purposes.

3. **Researcher’s compliance with patient privacy obligations.** Researcher represents, warrants and covenants that its transfer of Data to Recipient is compliant with all applicable rules, regulations and policies of any and all applicable Institutional Review Boards, the Health Insurance Portability and Accountability Act of 1996, as amended from time to time (‘‘HIPAA’’), patient informed consent documents, as well as all applicable federal, state and local laws, statutes, ordinances, rules and regulations regarding patient privacy and/or the transfer of the Data.

4. **Recipient obligations**.

a. *Collaboration Requirement.* Recipient agrees to work closely with the Researcher familiar with the Data provided hereunder.

b. *Informed Consents.* Recipient agrees to comply fully with study participants' informed consent documents as provided by Researcher.

c. *Confidential Information*. Recipient agrees that the Data shall be held in confidence by the Recipient.

5. **Term and right to terminate.** This Agreement shall be effective from the Effective Date until the completion of the Study unless otherwise extended or amended by agreement of the parties, or as earlier terminated pursuant to this Section. Either party to this Agreement may terminate this Agreement at any time for any reason or no reason, upon five (5) days prior written notice to the other party. Once the data have been transferred at the termination of the study, they cannot be withdrawn from the database (this would jeopardize the uniformity of the dataset).

6. **Data and intellectual property ownership.** Recipient shall have the sole and absolute right to create, control, own, have title in, disclose and use any Intellectual Property that relates to the subject matter of, or arises out of, the Study, the Data or the services performed by Researcher under this Agreement. Intellectual Property shall include but not be limited to any trademarks, service marks, copyrights, patents, inventions, products, equipment, processes, technology, computer programs, works of authorship, improvements, discoveries, developments, designs, data, know-how, ideas made or conceived or reduced to practice, in whole or in part.

7. **Costs.** The Researcher and Recipient agree to cover their own costs and expenses incurred in the performance of this Agreement.

8. **No warranties.** The institute in which the researcher conducted the study is not responsible for warranties, either express or implied, with respect to the data or other results arising from the study or with respect to any confidential information it may disclose to Recipient.

9. **Publication.** Nothing contained in this Agreement shall infringe or otherwise adversely impact the Recipient's sole, exclusive and unfettered right to publish any and all results of the Study, including the Data and any information relating to or derived from the Study or Data. Recipient shall provide appropriate acknowledgment of the Researcher in all publications arising from the Study, if possible, as outlined in the **uCARE Authorship and Publication Guidelines**.

10. **Liability.** Each party hereto agrees to be responsible and assume liability for its/his/her acts or omissions, and for the acts and omissions of those for whom it/he/she is in law responsible, arising out of or as a result of, or in connection with the conduct of the Agreement to the full extent required by law, and agrees to hold the other party harmless

from any such liability, limitation, reasonable legal fees and cost, and each party agrees to maintain reasonable and customary insurance coverage for the activities contemplated under this Agreement.

11. **General**.

a. **Relationship of Parties.** Nothing in this Agreement shall be construed so as to create a legal relationship of partnership, agency, joint venture, or employment among or between the parties.

b. **Governing Law**. This Agreement shall be governed by the laws of Canada, without reference to any choice of law rules that would result in the application of the substantive law of any other jurisdiction.

c. **Entire Agreement**. This Agreement represents the entire understanding of the parties (Researcher and his institute, and Recipient) with respect to the subject matter hereof. This Agreement supersedes any and all prior agreement or understandings, whether oral or written, among the parties.

d. **Inspection**. Researcher represents, warrants and covenants that the Data is accurate, objective and verifiable. The Researcher agrees and acknowledges that Recipient (or any other third-party as designated by Recipient), upon reasonable advanced notice to Researcher, shall have the right to audit, inspect, verify and/or validate the accuracy and objectivity of the Data, including the methodology and/or processes used in obtaining the Data.

Data Transfer Agreement for uCARE Study#: 2018-001

Signed by:

Date:	Date:
Principal Investigator's Name	uCARE Representative
Research Centre Name	