Data Storage, Access, Ownership, and Transfer Guidelines

IMPORTANT: All principal investigators and their research team/collaborators must read these guidelines prior to starting the study.

1. 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.

2. 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.

3. 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.

4. 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.

5. 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 institute.
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.

6. Agreement

☐ I have read the guidelines and acknowledge that I agree with them:

Signed on:

By:

On behalf of my research centre/institution: