Data Transfer Agreement

IMPORTANT: All principal investigators must digitally sign the last page to confirm their agreement on behalf of their research team and centre/institution.

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 _____, with a main address at _____ ("Institute"), _____ with an address at, _____ _____ ("Investigator"), and uCARE, with an address at 1155 Robert-Bourassa Blvd., Suite 1012, Montreal, Quebec, Canada, H3B 3A7 ("Recipient"). Recipient, Institute, and Investigator may be referred to, collectively, in this Agreement as the "Parties," and, individually, as a "Party." Institute and Investigator may be jointly referred to as "Researcher" provided that the rights and obligations of each of the Institute and Investigator remain joint and not several.

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. **"Sponsor"** means an industry partner or other funding source for the registry. 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.

"**Limited Data Set**" is Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;
(ii) Postal address information, other than town or city, State, and zip code;
(iii) Telephone numbers;
(iv) Fax numbers;
(v) Electronic mail addresses;
(vi) Social security numbers;
(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;

(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; and
(xvi) Full face photographic images and any comparable images.

"**Protected Health Information**" is Individually Identifiable Health Information that is (i) transmitted by electronic media, (ii) maintained in any medium constituting Electronic Media; or (iii) transmitted or maintained in any other form or medium. "Protected Health Information" shall not include (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g and (ii) records described in 20 U.S.C.§1232g(a)(4)(B)(iv). For instance, Protected Health Information includes information contained in a patient's medical records and billing records.

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: **uCARE2023-001**).
2. **Permitted uses**. Recipient will only use the Data for the purpose(s) and project(s) specifically set forth in the Appendix (the "Study"). However, it is acknowledged that the Limited Data Set 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 Limited Data Set 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 Limited Data Set. A separate clinical study research agreement between the Recipient (uCARE) and the Sponsor will be developed for each study. A Sponsor may use copies of the Limited Data Set delivered under contract for research and evaluation purposes. Recipient shall limit the use or receipt of the Data to only those individuals who need the Data Protected Health Information for the performance of the Activities. Recipient may not use the Protected Health Information for any commercial 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 collaborate 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 Study Results, 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 costs, 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 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.
    (e) No Party shall use, or authorize others to use, the name, symbols, or marks of another Party hereto or its staff for any endorsement purposes without prior written approval from the Party whose name, symbols or marks are to be used.
    (f) No Party may assign any of its/his/her rights or obligations under this Agreement without the prior written consent of the other Parties.
    (g) Each Party represents that it/he/she is permitted to enter into this Agreement; to consent to its conditions and that each has authority to sign this Agreement. This Agreement may be executed in counterparts and may be executed and delivered by facsimile, digitally or electronically by PDF and all such counterparts, facsimiles and PDF copies shall together constitute one agreement. The Parties agree that facsimile or PDF copies of signatures have the same effect as original signatures.

Data Transfer Agreement for uCARE Study # uCARE2022-001

Study Title: A Global Registry of Treatments and Outcomes for Benign Prostatic Hyperplasia

Signed by:

Principal Investigator	**Chair, SIU Office of Research**
Name:	Name: Mihir Desai, MD
Institution:	Institution: Société Internationale d'Urologie
Date:	Date:
Signature:	Signature: