**STUDY DEVICE CUSTODIAN AGREEMENT**

This Study Device Custodian Agreement (“**Custodian Agreement**”) is effective as of the \_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_, 2022, by and between \_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“**Sponsor**”) and Shands Teaching Hospital and Clinics, Inc. (“**Custodian**”). All capitalized terms not defined herein shall have the meaning ascribed to them in that certain Sponsor-Initiated Study Agreement between Sponsor and University of Florida (“**Institution**”), \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, Gainesville, FL, dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Study Agreement”).

**RECITALS**

**A.** Sponsor having engaged Institution to conduct a clinical research study titled “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_” (“**Study**”);

**B.** Sponsor having agreed to provide Institution with certain equipment (“**Study Device**”) and related components (“**Components**”), all as more particularly set forth on Exhibit 1 to this Custodian Agreement, as is necessary during the term of the Study for Institution to participate in the Study and solely for the purpose of carrying out the requirements of the Study Protocol that is the subject of the Study;

**C.** Custodian and Institution having arranged, separate and apart from this Custodian Agreement, to provide the physical site for conducting all or part of this Study (“Study Site”), such Study Site to be located at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_; and

**D.** Custodian being willing to maintain custody of the Study Device and the Components as set forth in this Custodian Agreement;

**NOW THEREFORE**, in consideration of the foregoing, and of the terms and conditions herein, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Custodian agrees to hold the Study Device and Components in its possession and custody throughout the term of the Study. No other right, title or interest in the Study Device or Components shall pass to Custodian. Custodian shall sign the Acknowledgement attached as **Exhibit 1** to acknowledge the date on which it received the Study Device and shall return a copy of same to Sponsor at the address designated thereon.

2. Custodian shall ensure that the Study Device and Components are properly secured and stored in a hygienic and adequately maintained location at all times while the Study Device and Components are in Custodian’s possession. Sponsor or Institution may monitor or audit the Study Device and Study Device storage location from time to time at reasonable times and upon reasonable notice to and approval of Custodian. Custodian shall notify Institution and Sponsor within five (5) days of a significant detrimental change in the adequacy of the Study Device storage location.

# **3. Title and ownership of the Study Device and unused Components will remain with Sponsor. Custodian agrees to use reasonable care to protect the Study Device and Components from theft, damage, or any other loss. Custodian shall keep the Study Device and Components free from all attachments, liens, security interests, and encumbrances, and shall promptly notify Sponsor if any of the foregoing is filed or claimed. Upon request of Sponsor, Custodian will provide Sponsor with documents (including financing statements under the UCC) necessary to protect Sponsor’s interest in the Study Device and Components.**

4. Custodian shall limit access to the Study Device and Components only to Sponsor, Institution and Investigator, and to Institution Study staff and Custodian’s Study Site staff responsible for receiving, the Study Device and who are under the supervision of Investigator or Sub-Investigators during the Study. Custodian shall not use, nor allow a health care professional or anyone else to use, the Study Device or Components for any other purpose.

5. Custodian agrees to reasonably cooperate with Institution and Investigator in regard to Institution’s responsibility to seek service on or replacement of the Study Device, if necessary, in accordance with Sponsor’s service and replacement procedures set forth on Exhibit 1. Custodian acknowledges that it shall be solely responsible for any separate obligations it may have to abide by applicable law, regulations, policies and procedures applicable to safe medical devices and any mandatory reporting of malfunctions and adverse events of medical devices.

6. Subject to Section 14, this Custodian Agreement shall commence and terminate in accordance with the Term of the Study Agreement.

# **7. Custodian acknowledges that the Study Device provided to Custodian for the Study must be returned to Sponsor at the end of the Study so that Sponsor can inventory and conduct any inspection required to ensure the integrity of the Study data. Custodian is under no** **obligation to purchase Study Device, Components, drill bits or any other products from Sponsor. Upon termination of the Study or of the Custodian Agreement, whichever is earlier, Sponsor will make arrangements to remove the Study Device and unused Components from Custodian at Sponsor’s sole expense.**

8. Custodian represents and warrants that: (i) Custodian shall not seek to collect separate reimbursement or other payments from any governmental or non-governmental payor, patient or other person with respect to its use of the Study Device and Components (including cost-based reimbursement or pass-through payments); and (ii) to the extent applicable, Custodian shall accurately report the Study Device and Components as zero cost items on any cost reports submitted to any federal or state health care program because Custodian incurs no cost for the use of the Study Device and Components in delivering patient care.

9. Custodian and Sponsor acknowledge that this arrangement is not related in any manner to the volume or value of Federal health care program business generated between any of the parties hereto. Custodian and Sponsor acknowledge and agree that the provision of the Study Device and the Components for use without cost in the care of a Study patient is intended solely to enable the Institution to conduct the Study under the Study Agreement and is not intended to constitute a discount to Custodian under the Federal Anti-Kickback Statute. Nonetheless, Sponsor hereby notifies Custodian that Custodian may have an obligation, if the value associated with the use of the Study Device or Components under this Agreement is deemed to constitute a discount, to report the discount and to provide, upon request by the Secretary of Health and Human Services or a state agency, information provided by Sponsor. Upon any such request by the Secretary of Health and Human Services or a state agency, Sponsor shall provide any and all necessary information to Custodian regarding the Study Device, Components and the Study. Furthermore, Sponsor shall refrain from doing anything that would impede Custodian from meeting its obligations to report any such deemed discount provided hereunder.

10. Custodian and Sponsor represent and warrant that they have the full right, power and authority to enter into this Agreement and to perform its obligations hereunder.

11. Custodian agrees that it has no right to any intellectual property of Sponsor or Institution as a result of this Agreement. Custodian has no right to use, access or publish any data collected in connection with the Study. Custodian shall not use the name, trademark, trade name, logo, or any adaptation thereof of Sponsor in any publication, press release, advertisement, announcement, promotional material without express written authorization from Sponsor. Sponsor shall not use the name, trademark, trade name, logo, or any adaptation thereof of Custodian in any publication, press release, advertisement, announcement, promotional material without express written authorization from Custodian.

12. Sponsor and Custodian shall each be responsible for the negligent acts or omissions of their own employees and agents while acting within the scope of their employment or contract during this Agreement. No party shall be liable for the negligent acts or omissions of any other party or any other party’s employees or agents. Custodian represents and warrants that it maintains general liability insurance at levels that are appropriate for the industry and that such insurance provides coverage for the loss, damage or destruction of property, including the Study Device, in the rightful custody of Custodian. Upon request, Custodian shall provide evidence of insurance coverage applicable to the Study Device.

## **13. This Agreement reflects the understanding of the parties with respect to Custodian’s and Sponsor’s obligations for the Study Device. This Agreement may not be assigned or amended by either party without the other party’s prior written consent. Both parties are independent contractors, and not a partners, agents, employees, or joint-venturers of each other. Neither of the parties nor their employees, agents or subcontractors, have any right or authority to bind or act on behalf of the other party. If a court of competent jurisdiction finds any provision of this Agreement legally invalid or unenforceable, such finding shall not affect the validity or enforceability of any other provision and the parties shall negotiate to revise the provision to make it valid and enforceable. If the parties cannot agree, the Agreement shall be performed in the absence of such provision. If such performance is impossible, this Agreement shall terminate. Florida law governs the terms of this Agreement without regard to the conflicts of laws principles.**

14. Representations and Warranties of Non-Exclusion from a Federal Health Care Program.

(a) Sponsor represents and warrants to Custodian that neither Custodian nor any of its owners, officers, directors, employees, independent contractors or agents (“Sponsor Representatives”) is an Ineligible Person. For purposes of the representations and warranties contained herein, an “Ineligible Person” is an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the federal health care programs as defined in 42 U.S.C § 1320a-7b(f) or in federal procurement or nonprocurement programs (the “Federal Health Care Programs”); or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in the Federal Health Care Programs. Sponsor further represents and warrants to Custodian that, to the best of the Sponsor’s knowledge, neither Sponsor nor any of the Sponsor Representatives is under investigation or otherwise engaged in conduct which may result in the Sponsor or one of the Sponsor Representatives, as the case may be, becoming an Ineligible Person.

(b) The foregoing representations and warranties shall be ongoing during the term of this Agreement, and Sponsor shall immediately notify Custodian of any change in their status. Any breach of the representations and warranties herein shall give Custodian the right to terminate this Agreement for cause as of the date of breach or at such other subsequent time as Custodian may elect.

IN WITNESS WHEREOF, the Parties have signed this Custodian Agreement by and through their respective authorized representatives.

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| **“Custodian”**  **Shands Teaching Hospital and Clinics, Inc.**  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **“Sponsor”**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |

**EXHIBIT 1**

**To the Study Device Custodian Agreement – Acknowledgement of Study Device Receipt**

**Study Device**

|  |  |  |
| --- | --- | --- |
| Material/Part# | Description | Quantity |
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*\* Serial No. will be provided by Sponsor after execution of the Study Device Agreement.*

**Related Components**

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| --- | --- | --- |
| Material/Part # | Description | Quantity |
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## SERVICE OR REPLACEMENT: Requests for service or replacement of an improperly functioning Study Device shall be initiated and processed in accordance with the following procedure. Institution is responsible for initiating, or overseeing the initiation of, service or replacement by calling \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_and specifically requesting assistance with the Study Device. Provide the Material/Part # and Serial Number of the Study Device and applicable fax and phone number. For second-day service, Institution must call before 4:00pm EST. Sponsor will issue a Return Authorization Number (“RA#”). To ensure proper receipt of the Study Device, Institution shall include correspondence identifying the problem with the Study Device and the RA# and shall clearly mark the shipping container with the RA#. Institution shall also include a decontamination certificate. Institution shall ship the Study Device to the appropriate Service Center as instructed by Sponsor. Sponsor will assume all risk of loss for the Study Device while it is in transit. Institution may carry out the procedure for assistance with service or replacement of the Study Device through an authorized representation, which may include the Custodian of the Study Device.

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## **Custodian acknowledges receipt of the: ❑ Study Device ❑ Related Components (check each as applicable) on the \_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2013 at \_\_\_\_\_\_\_\_\_\_\_\_\_\_am/pm (circle one).**

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| Shands HealthCare | RETURN A COPY OF THIS ACKNOWLEDGEMENT TO**:** |
| **By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| Title: |