DATA USE AGREEMENT

This Data Use Agreement (this "Agreement") is made by and between Yale University, a non-profit corporation, organized and existing under and by virtue of a special charter granted by the General Assembly of the Colony and State of Connecticut, with an address of Office of Sponsored Projects, 25 Science Park - 3rd Floor, 150 Munson St, New Haven, Connecticut 06511 ("Yale") and_____ _____ (enter name of principal investigator and principal investigator's institution, responsible for conduct of research, "Data User" and "Data User's Institution", respectively) with Effective Date the date of the last signature by the parties (Effective Date)

(collectively Yale and Data User shall be referred to as the "Parties").

Recitals

WHEREAS, MEDICAL DEVICES & DIAGNOSTICS GLOBAL SERVICES, LLC ("MDDGS"), acting on behalf of the Johnson & Johnson Family of Medical Device Companies, and Yale were parties to a certain Sponsored Research Agreement (the "Sponsored Research Agreement"), pursuant to which Yale undertook to accept or deny Data Use Proposals for Data Sets from Trials, with Trials defined as follows: (a) Trials are controlled, interventional clinical studies in patients of medical device or diagnostic products that have been provided any necessary marketing authorization from 2014 going forward to allow the marketing of the product under both the United States and European Union medical device legislative frameworks and (b) Trials do not include the following: (i) studies that were initiated prior to the effective date of the registration requirements for "applicable device clinical trials" under Title VIII of the Food and Drug Administration Act of 2007 (FDAAA); or (ii) studies that are not considered "applicable device clinical trials" under FDAAA, including but not limited to a small clinical trial to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes; or (iii) pre-clinical studies; each such medical device or diagnostic product being a "Product" for purposes of this Agreement); and

WHEREAS, Yale and MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, wish to make data from these Trials (the "Data") available to interested and qualified parties, guided by the underlying principles of independence, transparency and reproducibility and under the Sponsored Research Agreement, Yale may make such Data available; and

WHEREAS, effective as of January 14, 2015, Yale has made such Data available for use pursuant to the Yale Open Data Access (YODA) Project; and

WHEREAS, this Agreement is of mutual interest and benefit to Yale and Data User and will further the healthcare, educational, research and knowledge-advancement objectives of Yale in a manner consistent with its status as a non-profit academic institution; and

WHEREAS, the Parties desire to enter into this Agreement to provide for the access to Data for the purpose of promoting Research which will be used to create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health.

THEREFORE, in consideration of the mutual promises and covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Scope of Project

1.1 Research. Using the Data (see Section 2, Data) provided by Yale, Data User will conduct the analyses described in the attached Exhibit A, Research Proposal (the "Research"). Data User acknowledges and agrees that such Research Proposal and all application materials will be made publicly available by Yale.

1.2 No Funding. Yale will provide the Data (see Section 2, Data) at no cost to Data User. However, Data User shall bear its own costs regarding the conduct of the Research.

2. Data

2.1 Definition. The data that Yale will provide to Data User consists of Trial data that were provided to Yale by MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, (the "Data"). "Trials" are controlled, interventional clinical studies in patients of medical device or diagnostic products that have been provided any necessary authorization from 2014 going forward to allow the marketing of the product under both the United States and European Union medical device legislative frameworks. "Trials" do not include the following: (i) studies that were initiated prior to the effective date of the registration requirements for "applicable device clinical trials" under Title VIII of the Food and Drug Administration Act of 2007 (FDAAA); or (ii) studies that are not considered "applicable device clinical trials" under FDAAA, including but not limited to a small clinical trial to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes; or (iii) pre-clinical studies. The Data to be provided is intended to be completely de-identified consistent with the HIPAA privacy standards for de-identification set forth at 45 CFR § 164.514. Such Data shall not be modified or redacted by Yale or Data User (except with regards to de-identification) and any attempts to identify patients or providers or to suggest the identity of patients or providers are prohibited by this Agreement. Yale and

MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, make no guarantee the data will meet researchers' needs for analyses outlined in the Research Proposal.

2.2 Data Platform. Upon acceptance of the research proposal by Yale and full execution of this Agreement, Yale will provide Data User with access to the Data via a password-protected personalized account on a secure data sharing platform. Data User agrees to keep confidential the personalized access credentials and will not allow others to access the secure system using those personalized credentials. Data User shall not export the Data to any data platform other than the secure data platform to which access is granted or use the Data outside of the secure data platform to which access is granted without the prior written consent of Yale. Yale represents that it has full authority to grant access to the Data to Data User for the approved Research purpose. Yale, in conjunction with Data User, will determine a pre-specified timeframe for access to the platform, which will be dependent upon the number of trials requested within approved data requests (1-2 trials: 3-month access; 3-5 trials: 6-month access; 6 or more trials: 12-month access). Additional time may be requested by the Data User and subject to Yale approval. A maximum of three researchers will be granted access to the data platform per approved research proposal. Requests for additional credentials must be submitted in writing to Yale and will be evaluated on an individual basis. While not routine, if there are requests that require data dissemination outside of the secure data sharing platform, these will be considered and evaluated by Yale who will confer with MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, in the event that such dissemination could affect MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies.

2.3 No Direct Identifiers. The Data will not include any direct personal identifiers of the study subjects to whom the information relates, nor will it identify which clinical investigators or sites contributed the data for a particular subject. Within the Data, subjects and investigators are identified by unique identification numbers, and Data User will not have access to the keys that relate the identification numbers to the identities of the subjects or investigators.

3. Rights of Use of Data.

3.1 Data User may use the Data solely for the Research that is the subject of this Agreement, as defined in Exhibit A, Research Proposal, and may not use it for any other purpose. To conduct additional or different research, Data User must submit a separate Research Proposal, which must be approved by Yale and made part of this Agreement (or any subsequent agreements).

3.2 Data User may only disseminate its findings from the Research through peer-reviewed publication in the biomedical literature or a Scientific Meeting (as defined below), consistent with Section 8 of this Agreement.

3.3 Data User may not copy, retransmit or publicly post the Data, or transfer the Data for the purpose of allowing access to the Data by any third party not listed on the application (except as set forth in Section 5.2 below).

3.4 If Data User uses, or permits others to use the Data for any research not described in Exhibit A, Yale may, upon written notice to Data User, immediately terminate this Agreement in accordance with Section 10 and Data User acknowledges and agrees that Yale may publicly post any violation of this Agreement. Yale, or MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, will be free to pursue other legal remedies for non-compliance with this provision.

4. Data Access. After completion of the Research, expiration of the Term of this Agreement, or termination of this Agreement, whichever shall occur first, Data User's access to the secure data sharing platform will be terminated. In addition, if applicable, Data User will return to Yale or destroy (at Yale's option), all copies of full CSRs and supporting documentation. If Yale requests that Data User destroy the full CSRs and supporting documentation, Data User shall provide a certification evidencing such destruction within 30 days of the expiration date. Notwithstanding the foregoing, if the Data User's Publication (as defined below) is accepted for public disclosure in accordance with this Agreement, the Data User may retain rights to use the Data for verification of the Data User's Publication and to respond to inquiries regarding the Publication for five (5) years from the acceptance of such Publication. During this period, Data User may not use the Data to conduct additional or different research without submitting a new Research Proposal and obtaining approval from Yale.

5. Confidentiality of Data

5.1 Obligations of Confidentiality. Unless Yale provides prior written consent to do otherwise, Data User will

a. use Data, only as authorized by Section 3 above and disclose Data only as provided in the Research Proposal and only to the extent necessary for the performance of the Research and only after ensuring that such disclosures are protected by obligations of confidentiality substantially similar to those in this Agreement; and

b. not disclose the Data, to any other third parties, including but not limited to the publication or posting of the Data or any portion thereof, except as consistent with Section 8 of this Agreement.

5.2 Notification and Disclosure Required by Law. Data User will notify Yale immediately if it becomes aware of any disclosure in breach of the obligations in this Section 5 and will, at the request of Yale, take all such steps as are necessary to prevent further disclosure. If Data User is required by law to disclose any Data

during the term of this confidentiality obligation, such disclosure will not be considered a breach of this Agreement so long as Data User:

a. notifies Yale in writing as far as possible in advance of the disclosure so as to allow Yale to take legal action to protect the Data as appropriate,
b. discloses only that Data required to comply with the legal requirement, and
c. continues to maintain the confidentiality of all Data with respect to all other third parties.

5.3 Exclusions. The provisions of this Section 5 will not apply to any information that

a. is in the public domain at the date of this Agreement or which subsequently comes into the public domain other than by breach of this Agreement or any other confidentiality agreement;
b. is already in Data User's possession at the time of transfer from Yale and is free from any obligations of confidentiality;
c. is obtained by Data User, free from any obligations of confidentiality, from a third party who has a right to disclose it; or
d. is independently developed, as documented by written records, by individuals within Data User who had no access to Data.

5.4 Survival of Obligations. The obligations of confidentiality in this Agreement will survive termination of the Agreement and will continue for a period of five (5) years after termination.

6. Subject Protection. The Data may contain certain information that can be used by itself or in combination with other available information to identify a specific study subject ("Study Subject Personal Data").

6.1 No Re-Identification. Data User will not make any attempt to re-identify any of the study subjects.

6.2 Compliance with Applicable Law. In the performance of the Research under this Agreement, Data User will comply with all applicable national, regional, and local laws relating to information privacy.

6.3 Non-Disclosure. Without express written authorization from Yale, Data User will not disclose Study Subject Personal Data to any third party other than (1) employees, contractors, or subcontractors of the Data User or Yale on a need to know basis or (2) regulatory authorities, upon lawful request by such authority.

6.4 Safeguards. Data User will use electronic, physical, and other safeguards appropriate to the nature of the information to prevent any use or disclosure of

Study Subject Personal Data other than as provided for by this Agreement.

7. Reporting and Use of Results

7.1 Safety. Data User shall notify MDDGS immediately of any safety concerns identified in conducting the Research. Data User agrees that MDDGS and/or an entity that is part of the Johnson & Johnson Family of Medical Device Companies, in their sole discretion, may inform appropriate governmental authorities, health care providers, and the general public regarding any such safety concerns.

7.2 Reports. Data User will provide Yale with a report describing the results of the Research at the time that the Research is completed and, if accepted for publication, upon expiration of this Agreement. The report can take the form of a manuscript for publication (see Section 8, Publication). If Data User does not conduct the Research Proposal as described, Data User will notify Yale and Yale may terminate the Agreement in accordance with Section 10.

7.3 Use of Research Results. The Research results will belong to Data User and may be retained by Data User. However, Yale is free to publicly post the results after DUA expiration with appropriate acknowledgment of Data User.

7.4 Surveys. Data User agrees to complete periodic surveys by Yale about the use of the Data and progress on the Research, including information about results and presentations that are not confidential. The purpose of this survey is to allow the study of this model of data dissemination and the products that are produced from it.

8. Publication. Yale supports academic freedom and expects that Data User will produce peer-reviewed publication(s) in biomedical literature or at a meeting of a medical society or clinical research society ("Scientific Meeting"). Data User will provide Yale a copy of any publication, presentation, abstract or other public disclosure (collectively "Publications") at the time of submission for publication, which notice shall consist of the proposed title of the Publication, the name of the journal, and an estimated date of when the Data User expects it might be published. Yale shall then provide a copy to MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies.

Redaction of Data. Data User will not include Data, or portions thereof, in such Publications.

8.1 Acknowledgment. Data User will acknowledge Yale and MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, as the source of the Data in any publication of the Research; such acknowledgement

shall include a reference to the Yale University Open Data Access Project and reference the appropriate unique application identification number.

a. This specific statement must be referenced in all dissemination of findings: "This study, carried out under YODA Project # XXXX, used data obtained from the Yale University Open Data Access Project, which has an agreement with MEDICAL DEVICES & DIAGNOSTICS GLOBAL SERVICES, LLC, acting on behalf of the Johnson & Johnson Family of Medical Device Companies. The interpretation and reporting of research using this data are solely the responsibility of the authors and does not necessarily represent the official views of the Yale University Open Data Access Project or MDDGS, or the Johnson & Johnson Family of Medical Device Companies.

8.2 Other Publication Venues. If Data User wishes to make its results public other than via a peer-reviewed publication in biomedical literature or at a Scientific Meeting, Data User shall request further review by Yale, Data User may only proceed upon receiving approval from Yale. Once published, findings can be disseminated in any additional media venue. No press release shall be issued by the Data User summarizing the research findings unless made under embargo in concert with publication through a peer-reviewed publication in the biomedical literature or at a scientific meeting.

9. Inventions. If analyses of the Data results in any invention or discovery ("Invention"), Data User grants, and will ensure that the inventor grants, to MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, a fully paid, perpetual, worldwide, non-exclusive, royalty-free license for all purposes to each such Invention. Such non-exclusive license will include the rights to (1) sublicense to MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, affiliates, contractors, or collaborators (including, without limitation, their licensors and licensees) working for the benefit of MDDGS, on behalf of the Johnson & Johnson Family of Medical Device Companies, or in connection with MDDGS, on behalf of the Johnson & Johnson Family of Companies, on any collaboration product or service, and (2) sublicense or assign to a successor in interest to some or all rights in a product of a company that is part of the Johnson & Johnson Family of Companies, to which the Invention relates. Data User further grants, and will ensure that the inventors grant, to MDDGS, on behalf of the Johnson & Johnson Family of Medical Device Companies, an option to obtain an exclusive worldwide license for all purposes, with full rights to sublicense and assign, to each Invention, under terms to be negotiated in good faith between the parties.

10. Term and Termination

10.1 Term. This Agreement will remain in effect for one (1) year from the Effective Date. At the discretion of Yale, this agreement may be eligible for renewal for

additional one-year periods for on-going projects and an additional 5-year period for completed projects.

10.2 Early Termination. Yale may terminate this Agreement early if Yale reasonably determines that it is impracticable to provide the Data as specified or upon discovery of a material breach of this Agreement by Data User, such termination will be effective immediately upon written notice to Data User. Either Party may terminate this Agreement after thirty (30) days written notice to the breaching Party, in the event of a material breach of the Agreement by the other Party. In the event of a material breach by the Data User, Yale shall determine, in its sole discretion, if the material breach may be cured. The written notice to Data User shall identify whether the material breach may be cured.

10.3 Survival of Obligations. Obligations relating to the Data, Confidentiality of Data, Subject Protection, Reporting and Use of Results, Publication, and Debarment will survive termination of this Agreement, as will any other provision that by its nature and intent remains valid after termination.

11. General Provisions

11.1 Enforcement: MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, shall be a third party beneficiary to this agreement and shall have an independent right to enforce Data User's obligations under this agreement. Yale may engage in surveillance efforts to determine if the Principal Investigator is in compliance with the Agreement.

11.2 Relationship of the Parties.

a. Independent Contractor. The relationship of Yale, MDDGS, the Johnson & Johnson Family of Medical Device Companies, and Data User is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

b. Authority. Neither Party has the authority to bind or obligate MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, or the other Party in any way, nor will it represent that it has such authority. Each Party warrants that it has full power and authority and has taken all necessary action and obtained all necessary authorizations, licenses, consents, and approvals to execute and perform this Agreement.

11.3 Conflict with Attachments. If there is any conflict between this Agreement and any Exhibits or other attachments to it, the terms of this Agreement control.

11.4 Modification. Any alteration, modification or amendment to this Agreement must be in writing and signed by the Parties.

11.5 Debarment and Exclusion. Data User certifies that it is not debarred under subsections 306(a) or (b) of the Federal Food Drug and Cosmetic Act [U.S. Generic Drug Enforcement Act of 1992; 21 USC 335a (a) or (b)], and that it has not and will not use in any capacity the services of any person debarred under such law in performing under this Agreement. Data User further certifies that it is not excluded from any federal health care program, including but not limited to Medicare and Medicaid. Data User will notify Yale immediately if either of these certifications needs to be amended in light of new information.

11.6 Assignment and Delegation

a. By Data User. Data User may not assign its rights or delegate or subcontract any of its duties under this Agreement without written permission from Yale. Data User will remain responsible to Yale for the performance of any delegated or subcontracted services authorized by Yale just as though Data User had performed them itself. Data User will ensure that such agreements require compliance with applicable provisions of this Agreement, including but not limited to the following Sections 3 Rights of Use of Data, 4 Data Access, 5 Confidentiality of Data, 6 Subject Protection, 7 Reporting and Use of Results and 8 Publication.

b. By Yale. Upon notice to Data User, Yale may assign rights and delegate duties under this Agreement to MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, or to a successor in interest in the rights of MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies.

11.7 Successors and Third Party Beneficiary. This Agreement will bind and inure to the benefit of the successors and permitted assigns of each Party. Yale and Data User expressly acknowledge and agree that MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, shall be a third party beneficiary to this Agreement and MDDGS, acting on behalf of the Johnson & Johnson Family of Medical Device Companies, shall have an independent right to enforce any Parties' obligations under this Agreement.

11.8 No Use of Name. Neither Party will use the name of the other Party, or MDDGS, or the Johnson & Johnson Family of Medical Device Companies, or any of their personnel, in any public disclosure without prior written permission from the other Party (or MDDGS in the case of the contemplated use of its name or the name of the Johnson & Johnson Family of Medical Device Companies) except for publications in accordance with Section 8.

11.9 No Waiver. Failure to exert a right under this Agreement does not constitute a waiver of that right in the future. No waiver of any right is effective unless in

writing and signed by the Party who waives the right.

11.10 Entire Agreement. This Agreement, including Exhibits, represents the entire understanding between the Parties relating to this subject matter. This Agreement supersedes all previous agreements between the Parties (oral and written) relating to this subject matter, except for any obligations that, by their terms, survive termination.

11.11 Severance. If any provision of this Agreement is determined to be illegal or unenforceable, that provision will be severed from the Agreement and the remainder will remain valid, legal, and enforceable, provided that the surviving portion materially comports with the original intent of the parties.

11.12 Choice of Law. This Agreement is governed by the laws of the state of Connecticut without giving effect to its conflict of laws provisions.

11.13 Notices. The parties will deliver notices and other communications relating to this Agreement by hand, by courier, by a postage-paid traceable method of mail delivery to the address below, or such other address that a party may later designate by notice to the other party in accordance with this Section.

To Yale:

Yale University
25 Science Park-3rd Floor
150 Munson St
New Haven, Connecticut 06511
Attn: Office of Sponsored Projects

With a copy to:

Harlan Krumholz, MD
Yale Center for Outcomes Research and Evaluation (CORE)
1 Church Street, Suite 200
New Haven, CT 06510
Attn: Yale University Open Data Access (YODA) Project

To Data User:

_____
_____
_____
_____

To MEDICAL DEVICES & DIAGNOSTICS GLOBAL SERVICES, LLC:

Attention: MD&D Chief Medical Officer
410 George Street
New Brunswick, New Jersey 08901

11.14 Force Majeure. Yale shall not be liable for any failure to perform as required by this Agreement, to the extent such failure to perform is caused by any reason beyond Yale's control, or by reason of the following: labor disturbances or disputes of any kind, accidents, failure of any required governmental approval, civil disorders, acts of aggression, acts of God, energy or other conservation measures, failure of utilities, mechanical breakdowns, material shortages, disease or similar occurrences.

12. Certifications. Data User represents and certifies that the Data and Research will be used for scientific purposes and shall not be used for any commercial interests or in pursuit of litigation. Data User further represents and certifies that the application and/or registration submitted to obtain access to the Data is true and accurate and, if the representations made therein are no longer true or accurate, Data User will notify Yale immediately. Data User represents and certifies that it will not publicly post the Data, or any portion thereof. Data User acknowledges and agrees that a failure to comply with any portion of this Section 12 shall be a material breach of this Agreement.

11. Indemnification

The Research is not designed, sponsored, or managed by Yale and Yale provides no indemnification for study conduct. However, the Data User will indemnify and hold harmless Yale and its faculty, employees, students, officers, directors, and agents, MDDGS, the Johnson & Johnson Family of Medical Device Companies, and their employees and agents (collectively, "Indemnified Parties") from any losses (including reasonable costs of defending claims that result from Data User's use of the Data, Research, Invention, report or results). Yale shall promptly notify Data User upon learning of the institution, or threatened institution, of any such liability, claims, lawsuits, losses, damages, costs and expenses.

Read and Acknowledged by:

DATA USER

By: _____

Name: _____

Title: _____

Date: _____

Agreed to and Accepted by:

YALE UNIVERSITY

By: _____

Name: _____

Title: _____

Date: _____

DATA USER'S INSTITUTION

By: _____

Name: _____

Title: _____

Date: _____

EXHIBIT A – Research Proposal