

CRP BUSINESS ASSOCIATE AGREEMENT

This **CRP BUSINESS ASSOCIATE AGREEMENT** (“Agreement”) is made and entered into as of the ___ day of _____, 2019 (“Effective Date”) by and between _____ (the “Participant”) and MOREHOUSE SCHOOL OF MEDICINE, a Georgia non-profit corporation (“Morehouse”).

RECITALS

WHEREAS, the parties have executed a Network Participation Agreement as of the date hereof (the “Network Participation Agreement”), whereby Morehouse will provide (or caused to be provided) certain administrative services (the “Services”) on behalf of the Participant in connection with certain clinical research conducted by the Participant or physicians engaged or employed by the Participant who are listed on Exhibit A hereto, as amended from time to time, (collectively, the “Physicians”) as part of the Participant’s participation in the Morehouse Clinical Research Pathways and Registry (“**CRP**”);

WHEREAS, Morehouse in the conduct of its duties under the Network Participation Agreement will receive, have access to or create Protected Health Information (“PHI”) (as such term is defined in the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder, including the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164 (“Privacy Regulations”)) of the Participant’s patients, in order to provide the Services under the Network Participation Agreement;

WHEREAS, the parties acknowledge that the Participant and the Physicians (as applicable) are subject to the Privacy Regulations, and that Morehouse is a “business associate” (as such term is defined under the Privacy Regulations) of the Participant in fulfilling Morehouse’s obligations under the Network Participation Agreement;

WHEREAS, the Privacy Regulations require the Participant to enter into a contract with Morehouse and agree to certain protections for the privacy and security of PHI, and the Privacy Regulations prohibit the disclosure to or use of PHI by Morehouse if such a contract is not in place; and

WHEREAS, the purpose of this Agreement is to comply with the Privacy Regulations, including, but not limited to, the business associate contract requirements set forth in 45 C.F.R. § 164.504(e).

NOW, THEREFORE, in consideration of the foregoing premises and mutual representations and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows:

ARTICLE 1- DEFINITIONS

1.1 Definitions. Unless otherwise provided, capitalized terms shall have the same meanings ascribed to such term as set forth below:

- (a) “Disclose” and “Disclosure” mean, with respect to PHI, the release, transfer, provision of access to, or divulging in any other manner of PHI outside Morehouse’s internal operations or to other than its employees.
- (b) “Protected Health Information” means information that (i) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual; (ii) identifies the individual (or for which there is a reasonable basis for believing that the information can be used to identify the individual); and (iii) is received by Morehouse from or on behalf of the Participant, or is created by Morehouse, or is made accessible to Morehouse by the Participant (or the Physician(s), if applicable).
- (c) “Services” shall mean the administrative services to be provided by Morehouse as described in Articles 2 or 3 of the Network Participation Agreement.
- (d) “Use” or “Uses” mean, with respect to PHI, the sharing, employment, application, utilization, examination or analysis of such PHI within Morehouse’s internal operations as is necessary for Morehouse to perform its obligations under the Network Participation Agreement.

1.2 Undefined Capitalized Terms. Unless otherwise provided in this Agreement, capitalized terms shall have the same meanings ascribed thereto in the Privacy Regulations.

ARTICLE 2-OBLIGATIONS OF MOREHOUSE

2.1 Scope of Use and Disclosures of PHI by Morehouse. Morehouse:

- (a) shall Use and Disclose PHI only as necessary or appropriate to perform the Services under the Network Participation Agreement and as otherwise provided in this Agreement;
- (b) shall Disclose PHI to the Participant (and the Physician(s), if applicable) upon request;
- (c) may, as necessary for the proper management and administration of its business or to fulfill its legal responsibilities:
 - (i) Use PHI in its possession; and

(ii) Disclose PHI in its possession to a third party if (A) the Disclosure is required by law, or (B) Morehouse obtains written assurances from the third party to whom the PHI is Disclosed that the PHI will be held confidentially and Used or further Disclosed only as required by law or for the purpose for which it was Disclosed to the third party, and the third party agrees to notify Morehouse of any instances of which the third party becomes aware in which the confidentiality of the PHI has been breached.

Morehouse agrees not to Use or Disclose PHI for any other purpose.

2.2 Adequate Safeguards for PHI. Morehouse shall implement and maintain reasonable and appropriate safeguards to prevent the Use or Disclosure of PHI in any manner other than as permitted by this Agreement.

2.3 Reporting Non-Permitted Use or Disclosure. Morehouse shall report to the Participant each Use or Disclosure that is made by Morehouse, its employees, representatives, agents or subcontractors that is not specifically permitted by this Agreement. The initial report shall be made by telephone call to the Participant within forty-eight (48) hours from the time the Morehouse becomes aware of the non-permitted Use or Disclosure, followed by a written report to Participant no later than ten (10) business days from the date the Morehouse becomes aware of the non-permitted Use or Disclosure.

2.4 Mitigation of Harmful Effect. Morehouse agrees to mitigate, to the extent practicable, any harmful effect that is known to Morehouse of a Use or Disclosure of PHI by Morehouse in violation of the requirements of this Agreement.

2.5 Availability of Internal Practices, Books and Records to Government Agencies. Morehouse agrees to make its internal practices, books and records relating to the Use and Disclosure of PHI available to the Secretary of the U.S. Department of Health and Human Services for purposes of determining the Physician's compliance with the Privacy Regulations, subject to any applicable legal privileges.

2.6 Access to and Amendment of PHI. Morehouse shall, to the extent the Participant determines that any PHI constitutes a "designated record set" under the Privacy Regulations, (a) make the PHI specified by the Participant available to the individual(s) identified by the Participant or any Physician as being entitled to access and copy that PHI, and (b) make any amendments to PHI that are requested by the Participant or any Physician. Morehouse shall provide such access and make such amendments within the time and in the manner specified by the Participant to allow the Participant and the Physician(s) to comply with the Privacy Regulations.

2.7 Accounting of Disclosures. Upon the Participant's request, and within ten (10) days of the request, Morehouse shall provide to the Participant an accounting of each Disclosure of PHI made by Morehouse or its employees, agents, representatives or subcontractors. However, the parties agree that Morehouse is not required to provide an accounting of those Disclosures that are necessary to perform the Services if such Disclosures are for either payment or health care operations purposes, or both. Any accounting provided by Morehouse under this Section 2.7

shall include: (a) the date of the Disclosure; (b) the name, and address if known, of the entity or person who received the PHI; (c) a brief description of the PHI disclosed; and (d) a brief statement of the purpose of the Disclosure. For each Disclosure that could require an accounting under this Section 2.7, Morehouse shall track the information specified in (a) through (d), above, and shall securely maintain the information for six (6) years from the date of the Disclosure.

2.8 Other. Morehouse agrees not to make any Disclosure of PHI that the Participant or the Physician(s) would be prohibited from making.

ARTICLE 3-OBLIGATIONS OF THE PARTICIPANT

3.1 Obligations of the Physician. The Participant shall:

- (a) notify Morehouse of any current or future restrictions or limitations on the Use or Disclosure of PHI that would affect Morehouse's ability to perform the Services under the Network Participation Agreement or this Agreement;
- (b) notify Morehouse of any changes in, or revocation of, permission by any patient (or his/her authorized representative) of the Participant to Use or Disclose PHI, if such changes would affect Morehouse's ability to perform its obligations under the Network Participation Agreement or this Agreement;
- (c) include in the Participant's Notice of Privacy Practices that the Participant may disclose PHI for treatment, payment and health care operations purposes, as set forth in the Privacy Regulations;
- (d) notify Morehouse immediately of any change in its Physicians, and agree to modify Exhibit A accordingly, from time to time; and
- (e) obtain from individuals, consents, authorizations and other permissions necessary or required by any law applicable to the Participant and to enable Morehouse to fulfill its obligations under the Network Participation Agreement and this Agreement.

ARTICLE 4-TERM AND TERMINATION

4.1 Term and Termination. The term of this Agreement shall be the same as the term of, and may be terminated for the same reasons contained in, the Network Participation Agreement. Morehouse's obligations under Sections 2.7 and 4.2 shall survive the termination or expiration of this Agreement.

4.2 Disposition of PHI Upon Termination or Expiration. Upon termination or expiration of this Agreement and the Network Participation Agreement, Morehouse shall either return or destroy, **[in the Participant's sole discretion and in accordance with any instructions by the Participant]**, all PHI in the possession or control of Morehouse or its agents and subcontractors.

However, if the Participant and Morehouse agree that neither the return nor destruction of PHI is feasible for Morehouse, Morehouse may retain PHI provided that Morehouse: (a) continues to comply with the provisions of this Agreement for as long as it retains PHI, and (b) further limits Uses and Disclosures of PHI to those purposes that make its return or destruction infeasible.

ARTICLE 5-GENERAL PROVISIONS

5.1 No Third Party Beneficiaries. There are no third party beneficiaries to this Agreement.

5.2 Use of Subcontractors and Agents. Morehouse shall require each of its agents and subcontractors that receive PHI from Morehouse to execute a written agreement obligating the agent or subcontractor to comply with all the terms of this Agreement.

5.3 Relationship to Network Participation Agreement Provisions. In the event that a provision of this Agreement is contrary to a provision of the Network Participation Agreement, the provision of this Agreement shall control. Otherwise, this Agreement shall be construed under, and in accordance with, the terms of the Network Participation Agreement.

5.4 Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits the Participant and the Physicians to comply with the Privacy Regulations.

5.5 Amendments. This Agreement shall not be modified or amended without the prior written agreement of the parties. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Participant and its Physicians to comply with the requirements of the Privacy Regulations.

5.6 Assignment. The parties agree that neither party may assign such party's rights or obligations under this Agreement to another party without the prior written consent of the other party; provided however, that Morehouse may assign its rights and obligations hereunder to any corporate affiliate of Morehouse upon written notice to the Participant of any such assignment.

5.7 Entire Agreement. This Agreement and the Exhibits hereto (together with the Network Participation Agreement) sets forth the entire understanding between the parties with respect to the matters described herein. All prior understandings and agreements between the parties with respect hereto are expressly superceded by this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Business Associate Agreement effective as of the date stated above.

MOREHOUSE SCHOOL OF MEDICINE

PARTICIPANT

By: _____
Sandra Harris-Hooker, PhD
Vice President and Senior Associate
Dean for Research Affairs

By: _____
Print Name: _____
Print Title: _____
(if applicable)

EXHIBIT A

List of Participant's Physicians

(To be completed, if applicable.)