Bleeding Disorder Collaborative Agreement

This Agreement (the "Agreement"), effective as of January 1, 2016 (the "Effective Date"), is made between Washington State Health Care Authority ("HCA") and Bloodworks Northwest ("Contractor") (each a "Party" and collectively the "Parties").

Special Terms and Conditions

1. Definitions specific to Special Terms. The words and phrases listed below, as used in this Contract shall each have the following definitions:

   a. "BDOC" means Bleeding Disorder Collaborative.

   b. "HCA" means Health Care Authority.

   c. "WCBD" means the Washington Center for Bleeding Disorders.

2. The purpose of this contract is to provide a ~~research~~ collaborative network of hemophilia treatment centers focused on clinical practice improvement among patients with bleeding disorders.

3. Statement of Work. The Contractor shall provide the services, staff, subcontracts, and otherwise do all things necessary for or incidental to the performance or work, as set forth in Exhibit A, Statement of Work.

4. HUMAN SUBJECTS

   a. Contractor shall obtain Institutional Review Board ("IRB") review and approval of ~~the~~any studies involving human subjects~~y~~, including the informed consent form, in accordance with 21 C.F.R. Part 56. ~~and~~~~or Investigator shall obtain informed consent of the Subjects participating in the Study~~~~any studies involving human subjects in accordance with 21 C.F.R. Part 50.~~ Further, Contractor or Investigator shall obtain informed consent of the Subjects participating in any studies involving human subjects in accordance with 21 C.F.R. Part 50. ~~shall obtain Institutional Review Board ("IRB") review and approval of the study, including the informed consent form, in accordance with 21 C.F.R. Part 56.~~ Study Center shall supply HCA with evidence of IRB approval of both ~~the~~any ~~-studies~~ and the informed consent form, a copy of the IRB-approved informed consent form and a copy of any modified informed consent form later approved by the IRB. Contractor agrees not to begin enrolling Subjects until the IRB-approved informed consent form has been reviewed and approved.

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Comment [mr1]: I was under the impression that we were trying to avoid using the word "research" as the legislature is not involved in funding research efforts.

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Comment [RKJ2]: I would take this out – not sure we need it in the "statement of work"

b. Contractor, Investigator, and HCA each agree to comply with any and all laws relating to patient privacy applicable to such party. Without limiting the generality of the foregoing, Contractor and Investigator agree to take any and all acts necessary to ensure that it will be able to provide any and all study data to HCA. Such acts shall include, without limitation, obtaining in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder (collectively, "HIPAA") authorization from each Subject to provide Subject's Protected Health Information (or "PHI", as that term is defined in HIPAA) to HCA for the purposes of conducting the Study. HCA agrees that it will not disclose in any publication information that would readily reveal the identity of a Subject, such as name, social security number, telephone number or address, without the consent of such Subject.

~~3.~~c. c. Contractor and Investigator acknowledge that, pursuant to Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007, HCA may have an obligation to confirm the status of, and submit certain reports to the Centers for Medicare & Medicaid Services with respect to, Medicare beneficiaries who participate in the Study. This federal law reporting obligation applies when HCA agrees to reimburse for subject injury expenses. Subject to applicable law, Contractor and Investigator therefore agree to provide to HCA, through its authorized representative, personal information relating to Subjects, and to otherwise cooperate with HCA, as reasonably necessary for HCA to meet its Section 111 reporting obligations. HCA agrees that HCA and its representatives will use and disclose any such information provided only as reasonably necessary to meet Section 111 reporting obligations.

5. Monitoring. Contractor shall engage in periodic meetings with HCA staff as required by HCA Contract Manager. Progress reports documenting deliverables shall be attached to all invoices and submitted to the Contract Manager on the dates listed in the Statement of Work.

6. Publication. Contractor and/or Investigator are free to publish in reputable journals or to present at professional conferences the results of any studies conducted as part of this collaborative~~the Study~~.

7. Indemnification

a. HCA agrees to indemnify and hold harmless Contractor, Investigator, any Subinvestigators and Project Participants (collectively, "Study Center Indemnitees") from any and all liability, loss (including reasonable attorneys' fees), costs, or damage (collectively, "Damages") they may suffer as the result of third party claims, demands or actions (each, a third party "Claim") against them to the extent such Damages arise out of the activities carried out pursuant to the ~~study~~network activity, except to the extent any Damages arise from, or are alleged to arise from: a failure to adhere to the terms of the ~~study~~network activity, the negligence or willful misconduct on the part of any Study

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Center Indemnitee, a breach of this Agreement or any applicable federal, state or local law by any Study Center Indemnitee;

b. HCA's agreement to indemnify and hold harmless in section a is conditioned on the Contractor and Investigator obtaining from each affected Subject informed consent in compliance with 21 C.F.R. Part 50; and obtaining IRB review and approval in compliance with 21 C.F.R. Part 56.

c. Contractor agrees to indemnify and hold HCA harmless from any and all Damages as a result of a Claim to the extent such Damages arise from, or are alleged to arise from a failure to adhere to the terms of the study, the negligence or willful misconduct on the part of any Study Center Indemnitee, or a breach of this Agreement or any applicable federal, state, or local law by any Study Center Indemnitee.

~~4.~~d. Each Party's agreement to indemnify and hold the other harmless is conditioned on the Party seeking indemnification (i) providing written notice to the indemnifying Party of any Claim arising out of the indemnified activities as soon as reasonably possible after the Party seeking indemnification has knowledge of such Claim, (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Claim, (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defense of any such Claim, and (iv) not compromising or settling such Claim without the indemnifying Party's written consent. The indemnifying Party shall not settle a Claim in any manner that admits fault on behalf of the indemnified Party or imposes injunctive relief on the indemnified Party without such Party's prior written consent, which shall not be unreasonably withheld.

8. Inventions. Ideas, knowhow, inventions and other intellectual property made as a result of conducting the ~~Study~~collaborative are hereby collectively defined as "Inventions." Contractor represents that all Project Participants are required to assign all Inventions to the Contractor. ~~Inventions shall be the sole and exclusive property of Bloodworks.~~

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9. Compliance. Contractor and Investigator shall conduct the ~~Study~~work in accordance with all applicable federal, state and local laws and regulations, including, without limitation, those applicable portions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., and its implementing regulations.

10. Termination. Contractor by mutual agreement, may terminate the ~~Study and~~ this Agreement at any time upon thirty (30) days written notice to HCA.

11. Miscellaneous. This Agreement constitutes the entire understanding of the Parties with respect to the subject matter hereof, and no changes, amendments or alterations shall be effective unless in writing and signed by the Parties.

a. This Agreement is governed by the laws of the State of Washington, without regard to its conflict of laws principles.

b. Nothing in this Agreement is intended or shall be deemed to constitute an agency, joint venture, partnership, employer-employee or fiduciary relationship between HCA and Investigator or Contractor. All activities by Investigator and Contractor shall be independent acts of each Party, except as otherwise specifically provided herein, and neither Party shall incur any debts or make any commitments for the other Party, except as may be expressly provided herein.

c. The persons executing this Agreement represent and warrant that they have the full power and authority to enter into this Agreement on behalf of the persons or entities for whom they are signing. Faxed copies and scanned copies of original signatures shall be deemed as effective as original signatures.

~~5.~~12. Consideration. Total consideration payable to the Contractor for satisfactory performance of the work under this Contract is up to a maximum of $222,500 for the period of January 1, 2016 through June 30, 2016 and $249,000 for the period of July 1, 2016 through June 30, 2017 not to exceed a total of $471, 500 over the term of the Contract.

~~6.~~13. Funding Stipulations.

a. Indirect costs paid to any subcontractor shall not exceed 10% of the total amount remitted to that subcontractor.

b. Prohibition of Use of Funds for Lobbying Activities. The Contractor shall not use funds payable under this Contract for lobbying activities of any nature. The Contractor certifies that no state or federal funds payable under this Contract shall be paid to any person or organization to influence, or attempt to influence, either directly or indirectly, an officer or employee of a state or federal agency, or an officer or member or any state or federal legislative body or committee, regarding the reward, amendment, modification, extension, or renewal of a state or federal Contract or grant.

c. An unobligated balance may be carried over without prior approval from HCA.

d. The contractor may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original expiration date shown in the NoA if no term of award specifically prohibits the extension, no additional funds are required to be obligated by HCA, and the project's originally approved scope will not change.

~~a. Rebudgeting between cost categories stated in the deliverables included within the contract scope of work that does not exceed 25 percent of the total approved budget for a budget period shall be at the discretion of the contractor and not require prior approval from HCA.~~

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Bloodworks	Washington State Health Care Authority
By:	By:
Title:	Title:
Date:	Date:

The undersigned, as an employee of Contractor, has read this Agreement and understands his or her obligations thereunder.

Investigator:

By:

Date:

Statement of Work

1. Contractor shall collaborate with HCA staff and participate in the Bleeding Disorder Collaborative comprised of three representatives from HCA, three representatives from the largest organization in Washington representing patients with bleeding disorders, two representatives from state designated bleeding disorder centers of excellence, and two representatives of federally funded hemophilia treatment centers based in Washington.

2. Contractor shall plan, organize, and administer clinical research conducted on behalf of the Bleeding Disorder Collaborative, including:

    a. Organize, staff, coordinate research conducted through the BDOC;

    b. Develop an application process to recruit interested research facilities from across the state of Washington and Oregon to participate in the BDOC research projects.

    c. Executing contracts as necessary with subcontractors and research facilities to complete research;

    d. Coordinate and facilitate the evidence development, methodology, and review process including standards for the research, communication processes, and additional information needs;

    e. Collect and analyze data;

    f. Coordinate, facilitate, and assist with identification of the clinical experts to provide clinical input during development of evidence reports;

    g. Assist HCA in the development of a cost-benefit analysis regarding the use of evidence-based practices for specific populations in state-purchased health care programs.

3. Contractor shall make recommendations to HCA regarding the dissemination of the evidence-based practices to relevant health care professionals and support service providers and propose options for incorporating evidence-based practices into their treatment regimens; and

4. Deliverables

Deliverables	Cost	Date Completed
Identify Research Coordinator	$75,000	2/1/2016
Develop and maintain detailed project plan and schedule	$75,000	3/31/2016
Provide draft outline of research goals, objectives, design and methodology for developing evidence-based practice(s) to improve care to patients with bleeding disorders with specific attention to patient health quality outcomes and health care cost value. Identify major roles and	$36,250	4/30/2016

responsibilities as well as necessary resources (equipment, expertise, staffing, etc)		
Complete any required approvals needed for research, which may include but not limited to Internal Review Board, ~~others?~~	$36,250	7/1/2016
Provide full research project plan including study design, major milestones, participating clinics, process of data collection and analysis, ~~etc?~~	$150,000	
Recruit clinics for research participation. Manage, subcontract and oversee clinics that will be performing research activities. Coordinate all research elements, serving as the data coordinating center. Ensure all individual research projects adhere to timeline and milestones are met. Meet all subcontracting obligations and oversight.	$75,000	7/15/2016
Present completed research results, analysis, recommendations, training materials, and other outputs to HCA and Bleeding Disorder Collaborative	$20,000	4/1/2017
Develop Final Report for HCA and the Bleeding Disorder Collaborative to include, at a minimum, the following: • Complete description of study design, protocol and outputs, and evaluation. • Report on the analysis and recommendations stemming from project activities • Development of a cost-benefit analysis based on the research activities performed • Identify recommendations for an educational dissemination plan for providers, including ideas for content, training, and distribution plan. Identify practical options for incorporating identified evidence-based practices into health care treatment regimens	$4,000	5/31/2017