MINUTES OF THE SPECIAL MEETING OF THE
BOARD OF DIRECTORS OF THE
UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.

July 16, 2020

In Open Session

Members of the University of Louisville Research Foundation Board of Directors met virtually at 1:03 p.m. on July 16, 2020, with members present and absent as follows:

Present:
Ms. James Rogers, Chair
Ms. Bonita Black
Mr. Randy Bufford
Dr. Raymond Burse
Mr. Scott Brinkman
Mr. John Chilton
Ms. Sabrina Collins
Ms. Sandra Frazier
Ms. Diane Medley
Ms. Mary Nixon
Mr. John Smith
Prof. Krista Wallace-Boaz
Dr. Ron Wright

From the University:
Dr. Neeli Bendapudi, President
Dr. Beth Boehm, Executive Vice President and University Provost
Mr. Dan Durbin, Vice President for Finance and CFO
Mr. Thomas Hoy, General Counsel
Mr. Ralph Fitzpatrick, Vice President for Community Engagement
Mr. Vince Tyra, Vice President for Athletics and Athletic Director
Dr. Toni Ganzel, Vice President for Academic Medical Affairs
Ms. Mary Elizabeth Miles, CHRO & Assoc. Vice President for Human Resources
Ms. Sandy Russell, Vice President for Enterprise Risk, Audit and Compliance
Mr. John Drees, Sr. Assoc. Vice President for Communications and Marketing
Ms. Shannon Rickett, Assistant Vice President for Government Relations
Ms. Amy Shoemaker, Deputy General Counsel and Associate Athletic Director
Mr. Rehan Khan, Chief Information Officer and Vice Provost
Dr. Michael Mardis, Dean of Students & Vice Provost for Student Affairs
Dr. Robert Keynton, Special Assistant to the President
Prof. Reg Bruce, Associate Professor in the College of Business
Prof. Scott LaJoie, Assoc. Prof., School of Public Health & Information Sciences
Mr. Michael Wade Smith, Chief of Staff and External Affairs
Mr. Jake Beamer, Boards Liaison and Assistant Secretary

From UofL Health: Dr. Jason Smith, Chief Medical Officer

I. Call to Order

Chair Rogers called the roll. Having determined a quorum present, he called the meeting to order at 1:03 p.m.

Conflict of Interest Affirmation

The Chair reminded all members of the board of their responsibility to avoid conflicts of interest and appearances of conflicts of interest. He stated each member has received the agenda and related information for this Board of Directors meeting. Chair Rogers requested if any board member knows of any conflict of interest or appearance of conflict of interest with respect to any matter coming before the Board of Directors at this meeting, to please identify the conflict or appearance of conflict at this time.

No conflicts were identified.

Approval of Minutes, 4-23-2020

Ms. Frazier made a motion, which Ms. Nixon seconded, to approve the minutes of the April 23, 2020 meeting. The motion passed.

II. Action Item: Approval of Research Agreement with Norton for Pediatrics

Chair Rogers reminded directors that the Executive Committee tabled this item from its June 25, 2020 meeting, requesting more time to review the agreement.

Hearing no questions, Mr. Bufford made a motion, which Ms. Nixon seconded, to approve the

> **President's recommendation that the UofL Board of Trustees and the ULRF Board of Directors approve the Master Research Affiliation Agreement with Norton Hospitals, Inc., and Norton Children's Medical Group, LLC, as attached.**

The motion passed.

III. Adjournment

Having no other business to come before the board, Dr. Wright made a motion, which Ms. Collins seconded, to adjourn.

The motion passed and the meeting adjourned at 1:06 p.m.

Approved by:

Signature on file

Assistant Secretary

RECOMMENDATION TO THE UNIVERSITY OF LOUISVILLE BOARD OF TRUSTEES
AND RESEARCH FOUNDATION BOARD OF DIRECTORS REGARIDNG
A RESEARCH AGREEMENT WITH NORTON

Research Foundation Board of Directors – July 16, 2020
Board of Trustees – July 16, 2020

RECOMMENDATION:

The President recommends the UofL Board of Trustees and ULRF Board of Directors approve the Master Research Affiliation Agreement with Norton Hospitals, Inc., and Norton Children's Medical Group, LLC, as attached.

ULRF ACTION:
Passed X
Did Not Pass _____
Other _____
Signature on file
Assistant Secretary

BOT ACTION:
Passed X
Did Not Pass _____
Other _____
Signature on file
Assistant Secretary

6/17/2020
CONFIDENTIAL

MASTER RESEARCH AFFILIATION AGREEMENT

AMONG

NORTON HOSPITALS, INC.,

NORTON CHILDREN'S MEDICAL GROUP, LLC,

THE UNIVERSITY OF LOUISVILLE,

AND

THE UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC.

DATED AS OF [DATE], 2020

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MASTER RESEARCH AFFILIATION AGREEMENT

THIS MASTER RESEARCH AFFILIATION AGREEMENT (this "**Agreement**") is entered into as of [DATE], 2020 (the "**Effective Date**") among Norton Hospitals, Inc., dba Norton Children's Hospital ("**Norton**"), Norton Children's Medical Group, LLC ("**NCMG**" and, collectively with Norton, the "**Norton Parties**"), The University of Louisville (the "**University**"), acting on behalf of the University of Louisville School of Medicine (the "**Medical School**"), a component of the University, and University of Louisville Research Foundation ("**ULRF**" and, collectively with the University, the "**University Parties**"). The Norton Parties and the University Parties are collectively referred to herein as the "**Parties**" and individually as a "**Party**."

RECITALS

A. The University is a state institution of higher education, with programs in graduate and post-graduate medical education, research, and clinical medicine.

B. Norton owns and operates a full service freestanding pediatric hospital in the Commonwealth of Kentucky ("**Norton Children's Hospital**"), which serves as the primary pediatric teaching facility for the Medical School and engages in and has the personnel and facilities to support research. In addition, Norton owns and operates a pediatric medical office building, known as the Novak Center for Children's Health, which provides pediatric outpatient services.

C. The University and Norton have entered into that certain Master Pediatric Academic Affiliation Agreement (the "**Academic Affiliation Agreement**") that sets forth the terms and conditions of the restructured academic affiliation between the Parties in connection with the transfer of ownership and operation of the Pediatric Clinical Practice (as defined herein) to NCMG.

D. The University and the Norton Parties have entered into that certain Clinical Affiliation Agreement (the "**Clinical Affiliation Agreement**") that sets forth the terms and conditions of the restructured clinical affiliation between the Parties.

E. The Parties wish to establish a pediatric research collaborative through which the Parties will have joint oversight of strategic, financial, and operational planning with respect to clinical, translational, and population science research ("**Research**") conducted by the Pediatric Faculty (as defined herein) within the Norton Pediatric Enterprise (as defined herein), all on the terms and conditions set forth herein. Further, the Pediatric Faculty may conduct population science research or other basic science research outside of the Norton Pediatric Enterprise, and such research shall not be governed by the terms of this Agreement. Clinical and translational research may also be conducted outside Norton sites, as permitted by processes defined under the JPROC (as defined herein).

NOW, THEREFORE, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

In addition to the words and terms elsewhere defined in this Agreement, the following words and terms shall have the following meanings unless the context or use indicates another or different meaning or intent:

1.1 "**Academic Affiliation Agreement**" has the meaning set forth in the recitals.

1.2 "**AD**" has the meaning set forth in Section 2.5.

1.3 "**Affiliate**" means, with respect to any Person, any Person directly or indirectly controlling, controlled by, or under common control with, such other Person as of the date on which, or at any time during the period for which, the determination of affiliation is being made. For purposes of this definition, the term "control" (including the correlative meanings of the terms "controlled by" and "under common control with"), as used with respect to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management policies of such Person, whether through the ownership of voting securities or by contract or otherwise; and the term "Person" includes any successor to such Person.

1.4 "**Agreement**" has the meaning set forth in the introductory paragraph hereto.

1.5 "**Chargemaster**" has the meaning set forth in Section 5.4.1.

1.6 "**Clinical Affiliation Agreement**" has the meaning set forth in the recitals.

1.7 "**COI Policies**" has the meaning set forth in Section 6.4.2.

1.8 "**Confidential Information**" has the meaning set forth in Section 13.7.

1.9 "**Controversy**" has the meaning set forth in Section 11.2.

1.10 "**CSO**" has the meaning set forth in Section 2.5.

1.11 "**CTMS**" has the meaning set forth in Section 10.5.

1.12 "**Data Governance Council**" has the meaning set forth in Section 3.4.

1.13 "**Data Sharing Agreement**" has the meaning set forth in Section 9.1.

1.14 "**Department of Pediatrics"** has the meaning set forth in Section 7.4.1.

1.15 "**Dually Employed Faculty**" means all Pediatric Faculty employed by NCMG who receive "full-time" or "part-time" faculty appointments by the University or who are also employed by the University for their non-clinical time.

1.16 "**Effective Date**" has the meaning set forth in the introductory paragraph hereto.

1.17 "**Governmental Authority**" means any United States or foreign federal, national, supra-national, state, provincial, or local government, governmental, regulatory, self-regulatory or administrative authority, agency or commission or any court, tribunal or judicial or arbitral body or political or other subdivision, department or branch of any of the foregoing, provided, however, Governmental Authority shall not mean the University or any of its subsidiaries.

1.18 "**HHS**" has the meaning set forth in Section 8.2.

1.19 "**HIPAA**" has the meaning set forth in Section 9.1.

1.20 "**Initial Term**" has the meaning set forth in Section 12.1.

1.21 "**Integration Agreement**" has the meaning set forth in the Clinical Affiliation Agreement.

1.22 "**Investigator**" has the meaning set forth in Section 5.4.2.

1.23 "**IP Policy**" has the meaning set forth in Section 10.3.

1.24 "**JCOC**" has the meaning set forth in Section 6.1.

1.25 "**JPAC**" means the Joint Pediatric Advisory Committee established pursuant to the Academic Affiliation Agreement.

1.26 "**JPROC**" has the meaning set forth in Section 2.6.

1.27 "**Medical School**" has the meaning set forth in the introductory paragraph hereto.

1.28 "**NCMG**" has the meaning set forth in the introductory paragraph hereto.

1.29 "**NHC**" means Norton Healthcare, Inc.

1.30 "**NIH**" has the meaning set forth in Section 5.3.

1.31 "**Norton**" has the meaning set forth in the introductory paragraph hereto.

1.32 "**Norton Board**" means the Norton Board of Trustees.

1.33 "**Norton Brand**" has the meaning set forth in Section 10.6.

1.34 "**Norton Children's Hospital**" has the meaning set forth in the recitals.

1.35 "**Norton Facilities**" has the meaning set forth in Section 5.5.

1.36 "**Norton Parties**" has the meaning set forth in the introductory paragraph hereto.

1.37 "**Norton Pediatric Enterprise**" means Norton Children's Hospital, other children's hospitals or pediatric units within Norton-affiliated hospitals, NCMG, and other pediatric operations within the Norton system.

1.38 "**Off Campus**" has the meaning set forth in the Colleges and Universities Rate Agreement of the University of Louisville and University of Louisville Research Foundation, Inc. dated March 26, 2019.

1.39 "**Party**" or "**Parties**" has the meaning set forth in the introductory paragraph hereto.

1.40 "**Patient Information**" has the meaning set forth in Section 8.1.

1.41 "**Pediatric Clinical Practice**" has the meaning set forth in the Academic Affiliation Agreement.

1.42 "**Pediatric Faculty**" has the meaning of "**Current Pediatric Faculty**" as specified in the recitals of the Academic Affiliation Agreement (i.e. the faculty specified in Exhibit A of such who have a research appointment plus any pediatric faculty that are employed by the University as a Pediatric Physician (as defined in Section 1.40 of the Academic Affiliation Agreement) with a research appointment after March 1, 2020.

1.43 "**Person**" means any individual, partnership, limited partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture, Governmental Authority or other entity.

1.44 "**PRC**" has the meaning set forth in Section 2.1.

1.45 "**PRC Leadership**" has the meaning set forth in Section 2.5.

1.46 "**PRC Policies**" has the meaning set forth in Section 2.6.

1.47 "**PRC Research**" has the meaning set forth in Section 2.1.

1.48 "**Reliance Agreement**" has the meaning set forth in Section 6.3.

1.49 "**Renewal Term**" has the meaning set forth in Section 12.1.

1.50 "**Representatives**" means, with respect to any Person, any and all directors, officers, employees, consultants, financial advisors, counsel, accountants and other agents of such Person.

1.51 "**Research**" has the meaning set forth in the recitals.

1.52 "**Research Service**s" has the meaning set forth in Section 5.5.

1.53 "**Research Staff"** has the meaning set forth in Section 4.1.

1.54 "**Sponsor**" has the meaning set forth in Section 5.4.

1.55 "**Sponsored Research**" has the meaning set forth in Section 5.4.

1.56 "**SPRC**" has the meaning set forth in Section 2.7.

1.57 "**Study**" has the meaning set forth in Section 2.7.

1.58 "**Study Specific Work Order**" has the meaning set forth in Section 5.4.

1.59 "**Sunshine Act**" has the meaning set forth in Section 6.4.3.

1.60 "**Term**" has the meaning set forth in Section 12.1.

1.61 "**Third Party Payor**" has the meaning set forth in Section 7.2.

1.62 "**ULRF**" has the meaning set forth in the introductory paragraph hereto.

1.63 "**University**" has the meaning set forth in the introductory paragraph hereto.

1.64 "**University Brand**" has the meaning set forth in Section 10.6.

1.65 "**University Parties**" has the meaning set forth in the introductory paragraph hereto.

ARTICLE 2

CREATION OF PEDIATRIC RESEARCH COLLABORATIVE

2.1. Overview. The Parties shall create a pediatric research collaborative ("**PRC**") through which the Parties will have joint oversight of strategic, financial, and operational planning with respect to Research in all pediatric service lines initiated and conducted by Pediatric Faculty within the Norton Pediatric Enterprise ("**PRC Research**"). For the avoidance of doubt, PRC Research shall not include Research that involves primarily adult service lines, but may include Research that relates to both adult and pediatric service lines. The scope of PRC Research shall be further defined in the PRC Policies established pursuant to Section 2.6 below. Research that pertains only to adult service lines shall not be under the purview of the PRC. The Parties shall jointly oversee the leadership and operations of the PRC and jointly coordinate investment for the growth and enhanced capabilities of the PRC.

2.2. Independence; No Financial Commitments. Except as may be expressly agreed by the Parties in writing, each Party shall be responsible for its own expenses attributable to its participation in the PRC and in PRC Research. Norton shall retain ultimate control of the business and operations of the Norton Pediatric Enterprise. The Norton Board shall continue as the governing body of Norton in accordance with Norton's charter and bylaws. Nothing contained in this Agreement is intended to effect changes in the governing body of Norton or any of its Affiliates. The character and composition of the governing body of the University is not affected by this Agreement. As separate legal entities, the University (including the Medical School) and its Affiliates, including ULRF, and Norton and its Affiliates, including NCMG, each will be responsible for, and each will separately manage its respective financial affairs. Except as may be expressly agreed in writing: (a) neither Norton nor NCMG shall have any responsibility for the University Parties' respective financial obligations, liabilities, debts, commitments, or undertakings; and (b) neither the University nor ULRF shall have any responsibility for the Norton Parties' respective financial obligations, liabilities, debts, commitments, or undertakings.

2.3. Goals of Affiliation. The Parties will work collaboratively to establish the PRC as a leader in the discovery, translation, and validation of new knowledge in a way that improves child health and the quality and efficiency of health care delivery locally, nationally, and globally and supports the missions of both Parties. The Parties intend to conduct PRC Research in a combined, unified manner and in compliance with all applicable laws in order to efficiently achieve the shared objectives of the Parties.

2.4. Primary Research Site and Faculty Affiliation. The University Parties and the Norton Parties shall use the Norton Facilities within the Norton Pediatric Enterprise as the University Parties' primary site for all aspects of Research in all pediatric service lines initiated and conducted by Pediatric Faculty; provided, however, that nothing in this Agreement shall prevent any Party from participating in a multi-site study in which both sites within the Norton Pediatric Enterprise and sites not within the Norton Pediatric Enterprise participate. The University shall be listed as the primary faculty affiliation for all publications and presentations resultant from Research conducted through the PRC and Norton shall be listed as a secondary affiliation, as applicable, in a manner compliant with the rules for such of the respective publisher or the entity organizing the event at which the presentation will be made. For the avoidance of doubt, nothing herein shall prevent physicians who are not Pediatric Faculty but who hold privileges at one or more Norton Facilities within the Norton Pediatric Enterprise from conducting Research at such Norton Facilit(y)(ies) consistent with the applicable policies of the applicable Norton Facility; provided however, that such Research will not be governed by this Agreement. Pediatric Faculty will be given preference for use of Norton Facilities as their primary research site as determined by processes defined by the JPROC.

2.5. PRC Leadership. The PRC will be overseen by a leadership dyad consisting of an Administrative Director (the "**AD**") and Chief Scientific Officer (the "**CSO**" and, together with the AD, the "**PRC Leadership**"), each of whom shall be dually employed by Norton and the University. The PRC Leadership shall maintain a reporting relationship to the Chair of the University's Department of Pediatrics and the Norton Chief Research Executive, with consultation by the PRC Leadership and the Executive Vice President for Research and Innovation, the JPROC and/or JCOC as needed. Norton and the University will more clearly define the roles and responsibilities of the AD and the CSO as part of implementation planning for the PRC.

2.6. PRC Policies. The Parties, with the oversight of the Joint Pediatric Research Oversight Committee ("**JPROC**") shall use reasonable and diligent efforts to establish and maintain shared operating policies and procedures governing Research conducted through the PRC (the "**PRC Policies**") no later than November 1, 2020.

2.7. SPRC. The Parties shall establish and maintain a Scientific Protocol Review Committee ("**SPRC**") (which shall have no less than fifty percent (50%) of the members which are University selected) no later than November 1, 2020. The SPRC shall be responsible for reviewing and approving any and all proposed Research activities conducted within the Norton Pediatric Enterprise pursuant to this Agreement (each Research activity, a "**Study**") to ensure the scientific validity of the Study. Notwithstanding the foregoing, with approval of the JPROC, the SPRC may adopt policies that delegate approval of certain types of research activities to the CSO or other qualified faculty members as determined by the SPRC. The CSO shall be the Chair of the SPRC. The Parties shall make reasonable and diligent efforts to establish operating procedures

for the SPRC no later than November 1, 2020, which, among other things, shall set forth the scope, manner of acting, and specific responsibilities of the SPRC.

2.8. Contract Negotiation. Contract negotiations for all Sponsored Research engaged in by Pediatric Faculty within the Norton Pediatric Enterprise shall be conducted through the PRC which will consult with the appropriate administrative, compliance or legal representative of University Parties or Norton as appropriate. The Norton Parties and the University Parties hereby delegate the authority to negotiate on their behalf to the PRC; provided, however, that designated individuals at each of the Norton Parties, on one hand, and the University Parties, on the other hand, shall retain signature authority, unless otherwise mutually agreed by the Parties. Each Party shall predefine positions for key contract terms and shall develop an escalation matrix for decisions relating to terms outside such predefined standards which may include compliance aspects such as conflict of interest, research misconduct or risk management. For the avoidance of doubt, the PRC shall have access to the terms of all such contracts, including but not limited to the contract budget.

2.8.1. To assist with contract negotiations, the Parties will develop a clinical Study fee schedule, which shall include administrative start-up fees, for purposes of negotiation with each Sponsor for all Research conducted through the PRC.

2.8.2. All Sponsored Research submitted by Pediatric Faculty in connection with PRC Research shall be submitted and administered through the University's Office of Sponsored Programs Administration after approval of the relevant Study through the process established by the SPRC. Notwithstanding the foregoing, the University Parties shall provide the PRC with the terms of all such grants, including but not limited to the grant budget.

2.8.3. The University or ULRF shall serve as the primary recipient of all grants and contracts with Sponsors relating to PRC Research and all PRC Research funding shall flow initially to the University or ULRF, as applicable.

ARTICLE 3

JOINT PEDIATRIC RESEARCH OVERSIGHT COMMITTEE (JPROC)

3.1. Establishment of the JPROC. The Parties have established the JPROC as an advisory subcommittee of the JPAC responsible for making recommendations with respect to joint strategic and program planning to the JPAC and PRC Leadership. The JPROC shall have an equal number of representatives appointed by Norton and by the University, respectively. Representatives shall be individuals who can make major commitments on behalf of Norton and the University, respectively, related to matters relevant to PRC Research and shall include research leadership and physician-scientist representation. The Parties may also agree from time to time to invite others to attend or participate in meetings of the JPROC on a non-voting basis.

3.2. JPROC Responsibilities. The Parties shall use reasonable and diligent efforts to establish a charter for the JPROC no later than November 1, 2020, which, among other things, shall set forth the scope, manner of acting, and specific responsibilities of the JPROC, including the following:

3.2.1. Discussing adherence to the commitments of this Agreement;

3.2.2. Directing integrated strategic planning and program development;

3.2.3. Recommending and monitoring investments, including capital investments, relating to PRC Research;

3.2.4. Developing and recommending researcher recruitment plans to the JPAC;

3.2.5. Approving PRC marketing and Sponsor communication plans;

3.2.6. Establishing service level agreements, productivity metrics, and other key performance indicators that will be included in all employment contracts related to the PRC with NCMG and University maintaining such for their respective employees (or both in the case of dual employees);

3.2.7. Reviewing monthly financial and operational reports;

3.2.8. Defining the roles, responsibilities and costs associated with the administration of PRC Research and recommending a specific allocation of recovered indirect costs on an annual basis subject to the terms of Section 7.4 below;

3.2.9. Development of templates and processes for investigator initiated studies funded internally by University Parties or Norton Parties or by external sources which may result in an amendment to this Agreement and an additional Study Specific Work Order template;

3.2.10. Recommending changes to Pediatric Faculty and Research Staff effort allocation on a quarterly basis;

3.2.11. Approving the appointment or removal of the PRC Leadership; and

3.2.12. Reviewing and recommending for signature by the parties, in conjunction with JCOC where appropriate, implementation agreements resulting from the implementation planning efforts which are planned to be completed by November 1, 2020.

3.3. JPROC Operations.

3.3.1. The JPROC will meet monthly for the first six months following the Effective Date and at least quarterly thereafter.

3.3.2. The JPROC may establish such committees, subcommittees, or task forces, standing or *ad hoc*, as it deems appropriate from time to time. In all cases, the specific membership and charge of such committees and subcommittees shall be subject to the approval of the JPROC, and the membership of such committees and subcommittees shall include equal representation from Norton and the University except as otherwise agreed to by the Parties.

3.3.3. The PRC Leadership and other Representatives of the respective management teams of Norton and the University, while not members of the JPROC, will attend JPROC meetings regularly to provide needed support and input as well as participate in the

committees, subcommittees, and/or task forces. JCOC representatives may attend JPROC meetings as needed or requested to discuss or address PRC compliance matters.

3.4. Performance and Financial Data. Each Party's access to performance, quality, safety, financial, and research volume data or data reports related to PRC Research shall be as needed to fulfill their respective regulatory, compliance and sponsor obligations. Should such reports include protected health information, such access is subject to the approval of NHC's existing Data Governance Council (the "**Data Governance Council**") on a case-by-case basis. All such data sharing shall comply with HIPAA and any other applicable laws.

ARTICLE 4

RESEARCH STAFF AND PHYSICIANS

4.1. Employment of Research Staff. Any non-physician research staff hired on and after the Effective Date, including research nurses, clinical research coordinators, and all other non-physician academic, business, administrative, or clinical support staff ("**Research Staff**") hired in conjunction with Research conducted through the PRC shall be hired by and solely employed by NCMG with the exception of the PRC Leadership as specified in section 2.5.

4.1.1. The University or one of its Affiliates shall continue to employ existing Research Staff; provided, however, that the Parties intend to transition all employment of existing Research Staff to NCMG, unless the Parties mutually agree otherwise following due diligence and implementation planning.

4.1.2. The Parties shall discuss the possibility of NCMG leasing Research Staff employed by NCMG and that engage in PRC Research to the University pursuant to an employee lease agreement or vice versa, as needed.

4.2. Dually Employed Faculty. The Parties agree that all PRC Research activities, including clinical trials, will be categorized under the academic work assignment of any Dually Employed Faculty under the Annual Pediatric Faculty Work Plan (as defined in the Academic Affiliation Agreement).

4.3. Recruitment. The Parties shall jointly develop a strategic Pediatric Faculty and Research Staff recruitment plan to expand the Research capabilities of the PRC. The PRC Leadership shall oversee the recruitment of additional Research Staff for Research conducted through the PRC in accordance with such recruitment plan as it may be modified from time to time.

4.4. Insurance. The Parties shall procure and maintain insurance as follows:

4.4.1. The Norton Parties shall procure and maintain on behalf of the Pediatric Faculty and clinical Research Staff, inclusive of research nursing staff, employed by NCMG such insurance as is customary and appropriate to cover general liability, professional liability and medical professional/negligence liability, and any liability related to clinical research and clinical trials. Such insurance shall be with such carriers (which, in the case of self-insured items, may be Norton), in at least such amounts, contain at least such endorsements and cover at least such risks as those used or held by NCMG immediately prior to the Effective Date. Norton will provide

University a copy of the certificate of insurance and/or its self-insured items within thirty (30) days of Effective Date.

4.4.2. The University Parties shall procure and maintain on behalf of the clinical Research Staff, inclusive of research nursing staff, employed by the University such insurance as is customary and appropriate to cover general liability, professional liability and medical professional/negligence liability, and any liability related to clinical research and clinical trials. Such insurance shall be with such carriers (which, in the case of self-insured items, may be the University), in at least such amounts, contain at least such endorsements and cover at least such risks as those used or held by the University immediately prior to the Effective Date.

4.5. Oversight; Performance Reviews. The PRC Leadership, or their direct reports, shall be responsible for supervision of all Pediatric Faculty, in their capacity as researchers, and all Research Staff. The JPROC shall oversee the performance of the Pediatric Faculty, in their capacity as researchers, and all Research Staff. In the event either Norton or the University raises Pediatric Faculty or Research Staff performance issues for review by the JPROC, the JPROC shall make recommendations to the University, in the case of the Pediatric Faculty member in question, or the applicable employer, in the case of the Research Staff member in question, regarding corrective action. Should a compliance matter necessitate a recommendation for corrective action, the JCOC or the appropriate Norton or University compliance official will notify the applicable employer, operating within appropriate confidentiality obligations consistent with applicable law and the relevant employment agreement, of requested or recommended corrective and/or disciplinary actions. The policies and procedures of the respective employer would apply to such actions; provided, however, that regardless of the content of the policies or procedures of the respective employer, or the contents of any employment agreement with the employee in question, either the University Parties or the Norton Parties may remove a member of the Pediatric Faculty or Research Staff from a protocol or study as a result of performance issues or concerns regarding the compliance of such Pediatric Faculty or Research Staff member with Applicable Law, PRC Policies, or policies created by the JCOC pursuant to Section 6.2.1. Unless prohibited by law or the relevant employment agreement, and subject to imposition of appropriate confidentiality obligations, Norton and University will inform the other of resulting corrective action involving Pediatric Faculty and Research Staff. Notwithstanding, decisions regarding Pediatric Faculty appointments, renewals, terminations and promotions will be in accord with University Redbook and faculty personnel policies and procedures.

ARTICLE 5

RESEARCH SERVICES

5.1. Institution Oversight. Each Study Specific Work Order (as defined herein) for PRC Research shall set forth the Party or Parties responsible for the particular aspects of the applicable research, in accord with sections 2.8.2 and 2.8.3, including grant applications, sub-award oversight and authority, and contracts for research.

5.2. Institutional Review Boards ("IRBs"). All Research conducted through the PRC shall undergo human subjects protection review to the extent required by applicable law and University and the Norton Parties' policies for human subjects research. Processes and allocation

of responsibility and expectations for IRB review of PRC Research shall be set forth in a Study Specific Work Order. Unless stated differently in an applicable Study Specific Work Order, or unless the PRC elects to defer IRB review to a central IRB, the University's IRB shall be the IRB of record for PRC Research pursuant to a Reliance Agreement to be negotiated between Norton and the University. Notwithstanding anything to the contrary in any Study Specific Work Order, any Research conducted within the Norton Pediatric Enterprise by Pediatric Faculty shall be subject to the review and approval of the SPRC.

5.3. Signing Official. Except as otherwise agreed by the Parties and documented in a Study Specific Work Order, a University official shall be designated as the Signing Official (as such term is defined in the National Institutes of Health ("**NIH**") Glossary of NIH Terms) for PRC Research and such PRC Research shall be in accord with University policies for such Research.

5.4. Study Specific Work Orders. The Parties shall enter into one or more work orders (each a "**Study Specific Work Order**") in connection with any and all Studies approved by the SPRC, which may be for PRC Research funded by a University Party or otherwise funded in whole or in part by third parties such as federal agencies, state agencies, private industry or private foundations (each a "**Sponsor**") (such research, "**Sponsored Research**") substantially in the form(s) developed as a part of the implementation planning efforts targeted for completion by November 1, 2020 (or subsequently modified and approved by the JPROC) for the particular type of Sponsored Research. Exhibit A attached hereto is provided as an initial draft. Each Study Specific Work Order shall be a unique agreement that is independent of any other Study Specific Work Order. Upon initiation of the Study or any services contemplated by any Study Specific Work Order, whichever is sooner, no fees or rates set forth therein may be amended for the duration of a defined Study period or third-party grant/funding commitment absent mutual agreement by each of the Parties.

5.4.1. Chargemaster. To facilitate the preparation of Study Specific Work Orders, the Norton Parties will provide the University Parties with a chargemaster for Research Services, including all imaging and laboratory procedures to be used for PRC Research (the "**Chargemaster**"), which may be updated from time to time in Norton's sole discretion, provided, however, that such costs shall reflect fair market value (FMV) and any charges for a particular Study will be in accord with section 5.4 above, and shall be made available from the Norton Parties on a regular basis (or at such frequency as reasonably required by the PRC). The Chargemaster shall include all categories of fees designated, and account for any reasonable considerations required, by the PRC.

5.4.2. Study Protocols for Research. For any PRC Research to be conducted pursuant to this Agreement, the Pediatric Faculty member serving as the principal investigator (the "**Investigator**"), or their designee, will submit a Study protocol and other information regarding Study feasibility for approval through the process defined by the SPRC, consistent with the PRC Policies. Upon completion of the review in accordance with its operating procedures, the SPRC shall notify the Investigator, AD, and CSO in writing that the Study and budget have: (a) been approved; (b) been put on hold pending revisions; or (c) not been approved along with justification for this decision. If the SPRC or its delegates have proposed revisions to the Study protocol and/or budget, the Investigator will revise the protocol and/or budget and submit the revised documents for the SPRC's review. Notwithstanding the notice provisions set forth at Section 13.6 herein,

electronic mail shall constitute written notification for the purposes of the preceding sentence. The SPRC's final decision regarding the Study protocol and budget shall be sent to the Investigator.

5.5. Norton Research Services. Upon approval of each Study protocol in accordance with Sections 5.2 and 5.4.2 of this Agreement, the Norton Parties shall provide access to equipment, space, patients (including for recruitment, consenting, Study activity, and sample collection-related purposes), electronic medical records, and facilities that are owned or operated by Norton ("**Norton Facilities**") necessary to allow Pediatric Faculty to engage in all aspects of the approved PRC Research. Collectively, any such access or services required by the University Parties to conduct approved PRC Research, whether provided by the Norton Parties or in accordance with Section 5.6 below, shall constitute "**Research Services**." The Norton Parties shall also provide such additional Research Services as may be specifically defined in a Study Specific Work Order, which may include (a) administrative and professional support from Research Staff employed by NCMG and (b) use of supplies, furniture, fixtures, equipment, expendable supplies and the Norton Parties' physical space and access to Norton Facilities in accordance with the Master Space Agreement (as defined in the Clinical Affiliation Agreement).

5.6. Substitution for Research Services Provided by the Norton Parties. The University Parties may, subject to the approval of the SPRC and for any Study, engage any third-party vendor to provide Research Services instead of the Norton Parties if the Norton Parties lack the capability to furnish such services or as agreed upon by the JPROC. In such case, the Norton Parties shall cooperate with allowing access to Norton Facilities to such third part(y)(ies) to allow Pediatric Faculty and such third part(y)(ies) to engage in all aspects of the approved PRC Research.

5.7. Authorization to Execute. No Study Specific Work Order shall be valid and effective unless reviewed and signed by an authorized representative from each of the Parties.

5.8. Conflict. To the extent there is any conflict between the terms of this Agreement and a Study Specific Work Order, the terms of such Study Specific Work Order shall govern provided that any deviation from the terms of this Agreement and PRC Policies established pursuant to Section 2.6 must be noted specifically in the Study Specific Work Order.

5.9. Sponsor Requirements. If the Study is funded by a third party, in whole or in part, the Norton Parties acknowledge that the funding instrument or other agreement with the Sponsor may require additional terms, conditions, standards, limitations and/or other requirements be met and the Norton Parties agree to comply with, and to assist the University Parties in complying with, such additional requirements that are applicable to the performance of the Study as set forth in the applicable Study Specific Work Order.

5.10. Patient Access. In connection with providing the Research Services, the Parties will work together to inform patients within the Norton Pediatric Enterprise about research studies being conducted by Pediatric Faculty, and Pediatric Faculty will be granted access to patients who express interest in participating in such research studies consistent with the PRC Policies and the requirements of Article 9.

5.11. Investigational Pharmacy Services. The PRC shall evaluate the feasibility of providing investigational pharmacy services within the Norton Pediatric Enterprise.

5.12. Sponsor Supplied Equipment. Should Sponsor provide any equipment for use with the Study, the Party on whose premises the equipment is located will document the custody and control of such equipment and address any insurance requirements for loss or damage to the equipment, the details of which will be included in the Study Specific Work Order.

ARTICLE 6

COMPLIANCE

6.1. Establishment of Joint Compliance Oversight Committee (the "JCOC"). The Parties have established the JCOC as an advisory subcommittee responsible for making recommendations with regard to the compliance responsibilities associated with the PRC. The JCOC may make recommendations to the JPROC, the JPAC and the PRC Leadership as appropriate. The JCOC shall have an equal number of representatives appointed by Norton and by the University, respectively. Representatives shall be individuals who are knowledgeable and can address matters relevant to the compliance of PRC Research with applicable laws, regulations and industry practice. The JCOC may from time to time to invite others to attend or participate in meetings of the JCOC as needed.

6.2. JCOC Responsibilities. The Parties shall use reasonable and diligent efforts to establish a charter for the JCOC no later than November 1, 2020, which, among other things, shall set forth the scope, responsibilities and operations of the JCOC, including the following:

6.2.1. Develop policies and procedures (including appropriate training as appropriate) for the sharing of compliance responsibilities for PRC Research including the reconciliation and harmonization of existing policies among the Parties;

6.2.2. Develop and coordinate compliance matters arising from PRC Research;

6.2.3. Recommend roles and the particular Party's organization that will take the lead on particular compliance matters;

6.2.4. Develop data breach notification and mitigation process(es) in conjunction with the JPROC;

6.2.5. Develop templates, policies, memoranda of understanding and processes for addressing record keeping and sharing requirements for audits and investigations as contemplated in Article 8; and

6.2.6. Establishing and monitoring a policy and process for ensuring the billing to Third Party Payors is in conformity with any applicable Medicare coverage analyses and the terms and conditions of the agreement/award with the relevant Sponsor and is in conformity with the informed consent form and Medicare Secondary Payor rules.

6.3. IRB Policies; Work Orders. The University Parties, the Norton Parties, and their respective employees and agents shall conduct PRC Research and each Study in accordance with the terms of the applicable Study protocol and shall comply with all conditions imposed by the cognizant IRB, this Agreement, the reliance/authorization agreement with the cognizant IRB (each

a "**Reliance Agreement**") which when the cognizant IRB is other than University's IRB may include conditions set by University's IRB with respect to local issues, and any applicable Study Specific Work Order. The Investigator, in conjunction with a designated PRC staff member, shall immediately notify the cognizant IRB in writing upon receiving notice that any applicable IRB policy or procedure has been violated during the course of a Study, as per applicable regulations and IRB policy. Pursuant to Section 5.2, a Reliance Agreement will be executed between the University and Norton to govern compliance matters involving the cognizant IRB(s).

6.4. PRC Policies. The University Parties and the Norton Parties agree that during and in the conduct of a Study, their respective employees and agents shall comply with the PRC Policies.

6.4.1. Protocol or Policy Deviations Due to Medical Conditions. Notwithstanding anything in this Agreement, the Reliance Agreement, or a Study Specific Work Order to the contrary, if, in the medical opinion of the Investigator or in the opinion of the IRB of record, it is determined that reasonable alternatives to and/or deviations from the Study protocol, the PRC Policies or a Study Specific Work Order are required to ensure patient safety due to emergent or urgent medical conditions, any such alternatives or deviations shall not be considered a breach of this Agreement or the Study Specific Work Order. Should such medical issues require an amendment to the Study Specific Work Order, the Parties will negotiate in good faith to make such amendments. The JCOC may be consulted to facilitate resolution. The Investigator, in conjunction with a designated PRC staff member, shall report in writing such deviation or alternative and the reason(s) therefore to the cognizant IRB, in a timely manner as per applicable guidelines and regulations.

6.4.2. Conflict of Interest Assessment and Management. The Parties shall use reasonable and diligent efforts to establish and maintain conflict of interest assessment and management policies ("**COI Policies**") and procedures to govern Research conducted through the PRC no later than November 1, 2020. The COI Policies shall be developed to avoid duplication of effort wherever possible, shall meet the Public Health Service conflict of interest requirements (e.g. 42 CFR 50.604 (as amended)) and shall apply to all PRC Research. The Parties will review their respective COI Policies to identify any deficiencies that need revision such that the policies adopted as COI Policies applicable to PRC Research meet federal, state and Sponsor requirements. The Parties agree that during and in the conduct of a Study, their respective employees, agents and anyone performing Research Services in connection with the Study shall comply with the COI Policies. The Parties acknowledge and agree that the COI Policies may be modified by the Parties through coordination via the JCOC. Each Party, in accordance with the COI Policies, shall cooperate with any review(s) and associated determination(s) needed into any conflicts of interest, and shall answer any questions that the other Parties to this Agreement or the cognizant IRB may have and shall provide any additional documentation or financial disclosure information requested by the other Parties to comply with the COI Policies.

6.4.3. Payment Reporting. Each of the Parties acknowledge that under the provisions of Section 1128G of the Social Security Act, 42 U.S.C. § 1320a-7h (the "**Sunshine Act**"), as well as any similar state laws, Sponsors may be required to disclose certain payments and other transfers of value provided by or on behalf of the Sponsor to health care professionals and institutions. The Parties agree and acknowledge that, notwithstanding any provision to the

contrary in this Agreement, information about any payments and reimbursements provided hereunder may be disclosed without notice by Sponsors and may be made publicly available by the recipient federal or state agency, consistent with applicable law. For PRC Research that is Sponsored Research, the Parties agree, to the extent applicable, to promptly provide Sponsor (or the University Parties, to provide to Sponsor, as applicable) with any information reasonably requested by Sponsor for purposes of compliance with any such reporting obligation under the Sunshine Act or applicable state laws.

6.4.4. Compliance with Federal and State Laws. The Parties agree at all times to perform any Study or PRC Research in strict compliance with all applicable federal, state and local laws, guidelines, rules and regulations. Each of the Parties agrees to comply with generally accepted professional, clinical and research standards of care.

6.4.5. Accreditation Organizations. The Parties shall comply with all applicable statutes, rules, regulations, guidelines, and standards of any and all Governmental Authorities and accreditation bodies (such as The Joint Commission) relating to physicians, hospitals, and other health care facilities that apply to the provision of medical services and human subjects research.

6.4.6. Public Health. Notwithstanding anything in this Agreement or any applicable Study Specific Work Order to the contrary, if either Party discovers or learns that in connection with a Study, a present or imminent danger or health risk to the public or patients (including Study subjects) exists, the Parties shall cooperate to notify promptly all appropriate Persons regarding such danger or health risk, so that the danger or health risk may be abated or avoided.

6.4.7. Research Misconduct. As PRC Research is considered part of Pediatric Faculty's academic appointment, PRC Research shall be subject to the University's policies and processes regarding research misconduct. Each of the Parties agrees to comply with the applicable research misconduct regulations (which in the case of Public Health Service-funded research shall be those set forth at 42 C.F.R. Part 93), and the Norton Parties will cooperate with the University in so complying. The JCOC will be used to coordinate research misconduct activities among the Parties and develop any PRC Policies governing PRC Research to meet these applicable requirements.

6.4.8. Debarment and Exclusion.

6.4.8.1. Pediatric Faculty and NCMG Personnel. None of the Norton Parties, the Pediatric Faculty or Research Staff employed by NCMG or any third party performing Research under the Study Specific Work Order shall have been (a) debarred under 21 U.S.C. § 335a or have ever been convicted of any offense required to be listed under 21 U.S.C. § 335a, (b) excluded or threatened with exclusion from any federal or state healthcare program, pursuant to 42 U.S.C. § 1320a-7b or other comparable federal or state exclusion authority or relevant regulations, (c) assessed or threatened with assessment of civil monetary penalties pursuant to 42 U.S.C. § 1320a-7b or comparable federal or state civil monetary penalty authorities or relevant regulations, (d) under investigation or involved in debarment or disqualification proceedings conducted by a Governmental Authority, or (e) disqualified by the FDA or found by the FDA or any other Governmental Authority to have violated any federal, state or local laws, rules or

regulations relating to clinical investigations or Research generally. The Norton Parties shall promptly notify the University Parties and the PRC Leadership if any of the events in clauses (a) through (e) occurs during the Term of this Agreement (as defined herein).

6.4.8.2. The University Parties and University Personnel. Neither the University nor, to the extent the Research Services include services or support from Research Staff employed by the University or one of its Affiliates, Research Staff employed by the University or any third party performing Research under the Study Specific Work Order has been (a) debarred under 21 U.S.C. § 335a or has ever been convicted of any offense required to be listed under 21 U.S.C. § 335a, (b) excluded or threatened with exclusion from any federal or state healthcare program, pursuant to 42 U.S.C. § 1320a-7b or other comparable federal or state exclusion authority or relevant regulations, (c) assessed or threatened with assessment of civil monetary penalties pursuant to 42 U.S.C. § 1320a-7b or comparable federal or state civil monetary penalty authorities or relevant regulations, (d) under investigation or involved in debarment or disqualification proceedings conducted by a Governmental Authority, or (e) disqualified by the FDA or found by the FDA or any other Governmental Authority to have violated any federal, state or local laws, rules or regulations relating to clinical investigations or Research generally. The University Parties shall promptly notify the Norton Parties and the PRC Leadership if any of the events in clauses (a) through (e) occurs during the Term of this Agreement.

6.5. ClinicalTrials.gov Registration. The Parties agree that any Study registration and results reporting on clinicaltrials.gov is the responsibility of the Investigator of the Study in conjunction with the PRC administrative representative for posting and review of such registrations or, for industry sponsored clinical trials, the Sponsor unless the Sponsor has delegated such responsibility to the Investigator. The Parties shall comply with their respective obligations regarding clinicaltrials.gov in accordance with the underlying Study Specific Work Order, this Agreement, and applicable law.

ARTICLE 7

BILLING

7.1. Generally. Except as may otherwise be provided in a Study Specific Work Order, the University Parties shall pay the Norton Parties for those Research Services provided by the Norton Parties that are identified for payment in the Study Specific Work Order. The University Parties shall have no obligation to make payments for such activities or costs in the absence of an executed Study Specific Work Order.

7.2. Billing. The University Parties shall provide the Norton Parties with information necessary to identify those Research Services that may be billed to the University Parties (*i.e.*, Research Services paid by the Sponsor for Sponsored Research or another third party or for which the University Parties are responsible) and those Research Services that may be covered by federal healthcare programs and other third-party payors (collectively, "**Third Party Payors**"). Norton shall determine whether Research Services may be covered by Medicare or other Third Party Payors, and solely the Norton Parties shall submit claims to or otherwise bill Third Party Payors for Research Services. Any such billing of Third Party Payors shall be conducted in accordance with the terms and conditions of the Study and all applicable laws. No Norton Party shall (a) bill

a Third Party Payor for any item or service for which Norton bills any University Party, pursuant to a Study Specific Work Order or otherwise; or (b) bill any University Party, pursuant to a Study Specific Work Order or otherwise, for any item or service for which Norton bills a Third Party Payor.

7.2.1. The University Parties shall pay the Norton Parties for those services actually provided by the Norton Parties that are identified as Research Services in a Study Specific Work Order that may be billed to the University Parties. Payment for Research Services will occur within thirty (30) days following receipt of payment from the Sponsor.

7.2.2. The University Parties shall be responsible for charging the Research Services against the applicable grant or Sponsor's budget. The Parties will bill for the Research Services pursuant to the PRC Policies, the terms and conditions of the Study agreement or award with Sponsor, the Study Specific Work Order, and applicable law.

7.3. Rate of Payment. The University Parties shall reimburse the Norton Parties for those Research Services appropriately billed to the University Parties at the Norton Parties' standard, fair market value Study rates as set forth in the Study Specific Work Order.

7.4. Distribution of Recovered Indirect Costs. The recovered indirect costs of all PRC Research, as negotiated in the applicable agreement or award, shall be allocated as set forth in this Section 7.4; provided, however, that such allocation shall be subject to modification as required for compliance with applicable law and the terms of the applicable agreement or award.

7.4.1. For all Off Campus clinical trials conducted through the PRC with negotiated indirect costs budgeted under the then in effect Off Campus clinical trials indirect rate, which the Parties acknowledge is thirty percent (30%) for Off Campus industry sponsored trials as of the Effective Date, the University shall retain at least fifty percent (50%) of the recovered indirect costs and up to fifty percent (50%), but in no event less than twenty percent (20%) of the recovered indirect costs shall be distributed to the University's Department of Pediatrics (the "**Department of Pediatrics**") for purposes of funding the operations of the PRC.

7.4.2. For Research-related grants and contracts, including clinical trials, conducted through the PRC with negotiated indirect costs budgeted under the then in effect federal research on-campus rate, which the Parties acknowledge is fifty-six percent (56%) as of the Effective Date, the University shall retain the facilities portion of the recovered indirect costs and at least fifty percent (50%) of the administrative portion of the recovered indirect costs and up to fifty percent (50%), but in no event less than twenty percent (20%), of the administrative portion of the recovered indirect costs distributed to the Department of Pediatrics for purposes of funding the operations of the PRC. The same distribution methodology shall apply to Research-related grants and contracts where negotiated indirect costs are set at a level that is between the applicable Off Campus and on-campus rates.

7.4.3. For Research-related grants and contracts conducted through the PRC with negotiated indirect costs budgeted under the then in effect federal Off Campus rate, which the Parties acknowledge is twenty-six percent (26%) as of the Effective Date, the University shall retain at least fifty percent (50%) of the recovered indirect costs and up to fifty percent (50%), but

in no event less than twenty percent (20%), of the recovered indirect costs shall be distributed to the Department of Pediatrics for purposes of funding the operations of the PRC.

7.4.4. For all other Research-related grants and contracts conducted through the PRC with negotiated indirect costs budgeted at a rate below the then in effect Off Campus rate, which the parties acknowledge is twenty six percent (26%) as of the Effective Date, the University shall retain at least fifty percent (50%) of the recovered indirect costs and up to fifty percent (50%), but in no event less than twenty percent (20%), of the recovered indirect costs shall be distributed to the Department of Pediatrics for purposes of funding the operations of the PRC.

7.5. Records and Invoices. Norton and University will more clearly define the roles, responsibilities and costs associated with the administration of the PRC as part of the implementation planning of the PRC (as outlined in the responsibilities of the JPROC) and will agree upon a specific allocation of recovered indirect cost in writing on an annual basis. The Norton Parties shall maintain separate records of the costs of Research Services provided to the University Parties on a Study-specific basis. The Norton Parties agree to invoice the University Parties for Research Services provided at least on a monthly basis. The University Parties agree to reimburse the Norton Parties promptly for all undisputed, allowable costs owed under Study Specific Work Orders pursuant to this Agreement within either forty-five (45) days of the date of the Norton Parties' invoice or within thirty (30) days of receipt of payment from Sponsor following receipt of the Norton Parties' invoice.

7.6. Fair Market Value; No Referrals. The Parties agree that any remuneration contemplated by this Agreement or any Study Specific Work Order will (i) represent the fair market value for the services to be rendered, (ii) not be made in exchange for any explicit or implicit agreement or understanding that any Party purchase, lease, order, prescribe, or recommend the others' products or services or the products or services of a Sponsor or otherwise generate business for any Party or a Sponsor, and (iii) not be based on the volume or value of any referrals or business otherwise generated between the Parties or between a Party and a Sponsor. The Parties each agree that for each Study Specific Work Order (a) all claims that any Party submits for reimbursement to any Third Party Payor for any procedure that involves a Study drug or any other materials provided by or on behalf of the Sponsor at no cost to the Parties will accurately reflect the provision thereof by or on behalf of the Sponsor, (b) the Parties will not seek reimbursement from any Third Party Payor for any amounts paid by or on behalf of the Sponsor in connection with the Study, and (c) any equipment supplied by or on behalf of the Sponsor for use in the Study will be used solely in connection with the Study and will be returned to the Sponsor upon completion, abandonment or termination of the Study, unless otherwise required by the Sponsor.

ARTICLE 8

RECORDKEEPING, INSPECTION, AND AUDIT RIGHTS

8.1. Recordkeeping. The Parties agree to follow the Norton Parties' medical recordkeeping policies, the record keeping requirements set forth in any Study agreement or award and all applicable law and regulations governing retention of research records, and to maintain accurate, complete and current records with respect to Study subjects seen within the Norton Pediatric Enterprise under the care of Pediatric Faculty or Research Staff in connection with any

Study ("**Patient Information**"). The Norton Parties shall maintain original copies of all medical records relating to Research Services provided to Study subjects, and shall provide access for PRC staff to document research activities in the medical record as appropriate. The Norton Parties agree to make such records available to the University Parties and Sponsors for research, compliance (including but not limited to audit), and other related purposes in accordance with the PRC Policies, University Policies relative to research misconduct per Section 6.4.7 and applicable law. Further the University Parties agree to maintain accurate, complete and current research records with respect to Study subjects resulting from subjects seen within the Norton Pediatric Enterprise under the research auspices of the Pediatric Faculty or Research Staff in connection with any Study ("**Research Records**") and to maintain such Research Records in accordance with University policies, the record keeping requirements set forth in any Study agreement or award and all applicable record keeping laws. The Parties further agree to maintain and preserve Research Records for such periods as needed to comply with requirements of litigation (e.g. litigation hold), audits and investigations (e.g. FDA, research misconduct) or related compliance purposes.

8.2. Access to Books and Records. The Parties agree that if this Agreement or any agreements hereunder are determined to be a contract within the purview of § 1861(v)(l)(I) of the Social Security Act (§ 952 of the Omnibus Reconciliation Act of 1980) and the regulations promulgated in implementation thereof at 42 C.F.R. Part 420 then during this Agreement and for a period of four (4) years thereafter, each Party agrees to make available to the applicable Governmental Authority (*e.g.*, Comptroller General of the United States, the U.S. Department of Health and Human Services ("**HHS**") and/or their duly authorized representatives), access to the books, documents and records of such Party, and such other information as may be required by the Comptroller General or Secretary of HHS to verify the nature and extent of the costs of services provided by such Party. If a Party carries out the duties of the contract through a subcontract worth $10,000 or more over a twelve (12) month period with a related organization, the subcontract will also contain an access clause to permit access by the Secretary of HHS, Comptroller General and their representatives to the related organization's books and records. In the case in which a law or regulation applicable to the Study agreement or award and its associated Study Specific Work Order requires access by a party to this Agreement or a Governmental Authority or other third party to the books, documents and records of a Party, then during the Term of this Agreement and for a period of seven (7) years thereafter, such Party shall allow such access to permit such other party to verify, inspect or audit the services provided by such Party. In any such case of access to books or records, the Party accessing such books or records shall maintain appropriate confidentiality obligations regarding the protection of such records to the extent permitted by law.

8.3. Inspection. If any Governmental Authority notifies a Party that it will, in connection with a Study, inspect the Party's records, facilities, equipment or procedures, or otherwise take action related to a Study, such Party, if permitted by law and/or the Governmental Authority, shall promptly notify the PRC and allow the PRC Leadership or their designee to be present at the inspection/action and participate in any response to the inspection/action. The Party subject to such inspection shall provide the PRC Leadership with copies of any reports issued by the Governmental Authority and the Party's proposed response.

8.4. Audit Rights. To the fullest extent permitted by law and by the Study agreement or award, (a) each Party shall, in a timely manner, provide the other Parties with access to records for any Study subjects for whom Research Services have been provided pursuant to this Agreement

and (b) each Party shall cooperate with authorized staff of the other Parties in their monitoring and auditing of the Research Services provided pursuant to this Agreement, including assisting the other Parties in their review of the subjects' medical records. The Parties agree and acknowledge that pursuant to a clinical trial agreement for PRC Research that is Sponsored Research, the Sponsor may wish to conduct pre-site qualification visits, initiation visits, and provide on-site clinical monitoring. The Norton Parties agree that the Norton Parties will cooperate with the University Parties and Sponsor to provide for such on-site monitoring access, as may be further specified in a Study Specific Work Order.

8.5. Survival. The obligations of this Article 8 shall survive the termination of this Agreement and all Study Specific Work Orders.

ARTICLE 9

PATIENT PRIVACY AND DATA SECURITY

Notwithstanding the foregoing provisions of Article 8 or anything else in this Agreement or a Study Specific Work Order to the contrary:

9.1. Privacy Laws. The Parties agree and acknowledge that Pediatric Faculty may be provided access to Patient Information maintained by the Norton Parties for use in PRC Research. The use and disclosure of Patient Information shall comply with the PRC Policies, the data sharing agreement between Norton and ULRF dated August 7, 2018 (the "**Data Sharing Agreement**"), and with all applicable federal and state laws and regulations governing patient privacy and confidentiality of health information, including without limitation the Health Insurance Portability and Accountability Act of 1996, as may be amended from time to time, and implementing regulations thereto ("**HIPAA**"); provided, however, that the Parties shall amend and restate the Data Sharing Agreement in a form mutually agreed upon by the Parties no later than November 1, 2020. For the avoidance of doubt, to the extent any of the University's students or residents are permitted by Norton to have access to any information subject to the privacy standards (codified at 45 CFR, Parts 160 and 164) implementing the privacy requirements of HIPAA, the University shall require such students or residents to fully comply with all of Norton's requirements concerning HIPAA privacy with respect to uses and disclosures of protected health information for research purposes both during and following their assignment pursuant to this Agreement.

9.2. Conditions for Use and Disclosure of Patient Information. The Parties agree that all individually identifiable Patient Information related to PRC Research undertaken pursuant to this Agreement shall be used and disclosed only as contemplated by a Study Specific Work Order, any applicable HIPAA research authorization or IRB or privacy board-approved waiver of such authorization, the applicable Study or funding agreement, or as otherwise permitted by HIPAA or applicable law.

9.3. Data Security. All Research conducted through the PRC requiring external data submission, storage, or data transport on Norton servers, storage or data transport shall adhere to the Norton Parties' existing data security policies as may be modified from time to time for the purposes of PRC Research. Such Norton Parties' data security policies shall minimally meet the requirements for storage, data submission or data transport that the University would be required

to follow if such data were stored on University servers, storage or data transport. All Research data stored on University Parties servers, storage or data transport shall adhere to University Parties' existing data security policies as may be modified from time to time.

9.4. Data Breach Notification. By November 1, 2020 via the JCOC in conjunction with the JPROC, the Parties agree to develop data breach notification policies and procedures which shall minimally comply with applicable data breach notification and mitigation laws and regulations applicable to the respective Parties.

ARTICLE 10

INTELLECTUAL PROPERTY AND INFORMATION TECHNOLOGY

10.1. Intellectual Property Rights. The Parties understand that this Article 10 sets forth the general understanding for research collaboration between the Parties as described herein, and that the Parties may agree to different intellectual property-related terms in the context of specific studies to be conducted in Study Specific Work Orders.

10.2. Pre-Existing Inventions and Technology. The Parties recognize and acknowledge that, in any Study, certain pre-existing inventions and technologies may be (a) the separate property of the University Parties, the Norton Parties, or the Sponsor for Sponsored Research or (b) jointly-developed inventions. Any rights to or licenses to use such inventions or technologies shall be addressed in the Study Specific Work Order or made the subject of a separate agreement which agreement shall be attached to the Study Specific Work Order and incorporated therein and herein by reference. No Party shall have any claims to or rights in such separate or pre-existing jointly-developed inventions or technologies, except as may be set forth in such Study Specific Work Order or applicable separate agreement. Any disposition of pre-existing intellectual property of the University Parties contained within any Study Specific Work Order or Study agreement or award shall be negotiated in conjunction with the University's Commercialization EPI-Center.

10.3. New Inventions. The Parties shall use commercially reasonable efforts to establish no later than November 1, 2020 a jointly-developed intellectual property and commercialization policy governing any new invention that is conceived, created, adapted or reduced to practice as a part of the PRC Research endeavors (the "**IP Policy**"). The IP Policy shall take into account the University's intellectual property and commercialization policies in effect from time to time.

10.4. Intellectual Property and Third-Party Funding. The Parties agree and acknowledge that any rights to intellectual property (including, but not limited to, new inventions contemplated by Section 10.3 above) are subject, to the extent applicable, to the University Parties' third-party funding and sponsorship agreements with respect to any given Study. Any applicable Study Specific Work Orders shall incorporate the applicable terms and requirements of such agreements with respect to intellectual property restrictions.

10.5. IT Platforms. If Norton provides access to a secure data storage infrastructure for storage of Research Records for PRC Research purposes, access and use of all IT infrastructure provided by Norton for use by the PRC shall be subject to applicable policies and procedures which shall meet the requirements as outlined in Section 9.3 and those specified by Norton's IT Security

Department. The Parties acknowledge that Norton anticipates transitioning from its current clinical trial management system ("**CTMS**") and eRegulatory platform to Epic's CTMS. The Parties shall develop a plan by November 1, 2020 to ensure Pediatric Faculty and Research Staff engaged in PRC Research are provided access to all information technology systems that are necessary and appropriate to perform their unique function(s), following approval from appropriate personnel of NHC and the Norton Parties, NHC's IT Security Department, and the Data Governance Council and concurrence by the University Parties. Norton's IT Platforms will provide appropriate access (in accordance with Section 9.3) to any Research data which resides on University servers, storage or data transport should Pediatric Faculty or Research Staff need access to such Research data. Such access shall include access to other University IT Platforms as necessary for Pediatric Faculty to perform other University academic functions, such as University email and University licensed application systems such as Blackboard.

10.5.1. The University shall provide a mechanism(s) for those PRC staff who need access to those University systems required for the conduct of Research. Access to sponsored email accounts, when appropriate, will be administered by the PRC and overseen by the AD. Likewise, NHC will provide mechanism(s) for University employees to access Norton systems as required for the conduct of research. A technical coordination work group of representatives of University and NHC Information Technology/Security staff (the "**TCW**") will meet as needed to implement these mechanism(s). It is anticipated the TCW may continue as needed to coordinate ongoing technical changes to ensure continued access thereafter.

10.5.2. The University shall provide mechanism(s) for those PRC staff who need access to University financial and regulatory systems to access such systems. It is understood that such mechanism(s) are subject to standard University policies and procedures. As provided in Section 10.5.1 the TCW will assist in facilitating such access.

10.6. Branding; Use of Name. The Parties, with oversight from the JPROC, shall coordinate an approach to branding, communication, and marketing of the PRC. Subject to the terms of any Sponsored Research agreements between the University Parties and an applicable third-party funder, the University's name, logo and other trademarks, service marks and other identifying marks (the "**University Brand**") and Norton's name, logo and other trademarks, service marks and other identifying marks (the "**Norton Brand**") shall not be used by the other Party except in a manner and format agreed upon by the Parties (a) to identify the affiliation of the University and Norton and (b) for such other purposes as agreed upon in writing or otherwise permitted by the Clinical Affiliation Agreement, Academic Affiliation Agreement, and Integration Agreement. Any permitted use of the University Brand or the Norton Brand shall be subject to the terms of a mutually-agreeable license agreement to be executed between the Parties. Each Party agrees that it will not make any form of representation or statement in relation to any Study which would constitute an express or implied endorsement of any commercial product or service and that it will not authorize anyone else to do so without having first obtained prior written approval from the other Party.

ARTICLE 11

SPONSOR INDEMNIFICATION AND DISPUTE RESOLUTION

11.1. Sponsor Indemnification. The PRC, via the contract negotiation process outlined in Section 2.8, shall use reasonable best efforts to include the Norton Parties in any indemnification obtained from the Sponsor of any Sponsored Research conducted through the PRC. For the avoidance of doubt, the Norton Parties, in their sole discretion, may choose not to participate in a Study in which the Sponsor does not agree to indemnify the Norton Parties.

11.2. Dispute Resolution. The Parties acknowledge that issues, controversies, claims, or disputes may arise between them with respect to their rights, responsibilities, obligations, and liabilities under this Agreement or any Study Specific Work Order or relating to the business of the PRC (each, a "**Controversy**"). All Controversies unable to be resolved by discussions with the responsible individuals shall be submitted first to the JPROC, which shall use reasonable and diligent efforts to resolve such Controversy within thirty (30) days of such submission. If the JPROC is unable to resolve such Controversy within thirty (30) days of such submission, the Parties shall follow the dispute resolution process set forth in Section 9.1 of the Academic Affiliation Agreement.

ARTICLE 12

TERM AND TERMINATION

12.1. Term. This term of this Agreement shall commence on the Effective Date and continue through [December 31], 2025 (the "**Initial Term**"). This Agreement will thereafter be automatically renewed for successive five-year periods commencing on January 1 of each year (each a "**Renewal Term**" and together with the Initial Term, the "**Term**"), unless earlier terminated pursuant to Section 12.3 or unless either Party provides notice of its intent not to renew at least six months prior to the end of the Initial Term or the then-current Renewal Term, as applicable. For purposes of this Article 12, the Norton Parties, collectively, and the University Parties, collectively, shall each be referred to as a "Party."

12.2. Term of Study Specific Work Order. Each Study Specific Work Order shall take effect as of an effective date designated therein. Each Study Specific Work Order shall continue in full force and effect for the duration of the Study and unless and until specifically terminated in accordance with the terms of this Agreement or that Study Specific Work Order.

12.3. Termination. This Agreement may be terminated as follows:

12.3.1. By mutual agreement of the Parties;

12.3.2. By either Party with six (6) months' prior written notice to the other Party;

12.3.3. By either Party in the event of the termination of the Academic Affiliation Agreement;

12.3.4. By either Party in the event of the termination of the Clinical Affiliation Agreement;

12.3.5. By either Party in the event of a material breach of the other Party, if the breaching Party does not cure such breach within ninety (90) days of receiving written notice of the breach from the non-breaching Party, except that no such cure period shall be available in the event of a material breach that places in significant jeopardy the health or safety of patients, Study subjects, Pediatric Faculty, Research Staff, or the employees, residents, staff or volunteers of any Party (and that cannot be cured through immediate termination of a Study Specific Work Order pursuant to Section 12.4);

12.3.6. By either Party in the event of a restriction, limitation, suspension, termination, revocation, or exclusion of any Party's right to participate in the Medicare, Medicaid, or other federal or state governmental health care programs;

12.3.7. By the University Parties upon the termination or revocation by the Kentucky Cabinet for Health and Family Services of Norton Children's Hospital's hospital license or upon the loss of Norton Children's Hospital's The Joint Commission accreditation;

12.3.8. By the Norton Parties upon the Medical School's loss of its LCME or ACGME accreditation; or

12.3.9. By either Party in the event the other Party files or is subject to any voluntary or involuntary bankruptcy, receivership, assignment for the benefit of creditors, liquidation, dissolution, or similar proceeding.

12.4. Termination of Study Specific Work Orders. In addition to the termination rights provided under this Article 12, either Party may terminate any Study Specific Work Order immediately upon (a) written notice to the other Party upon identification of any medical risk that poses immediate hazard to Study subjects; (b) receipt of notice of regulatory action by the FDA or other agency as applicable terminating or suspending that Study; (c) upon termination of the Study by the Sponsor; or (d) withdrawal or suspension of IRB approval of a Study for any reason. Upon termination of a Study Specific Work Order, the University Parties shall remit payment to the Norton Parties for all Research Services provided prior to termination of such Study Specific Work Order and all non-cancelable commitments of the Norton Parties incurred thereunder prior to the date of termination for which University Parties receive payment from Sponsor.

12.5. Effect of Termination. In the event of termination or expiration of this Agreement, the Parties shall cooperate to develop a transition plan for the orderly termination of this Agreement, including processes to minimize the impact on ongoing PRC Research.

ARTICLE 13

MISCELLANEOUS

13.1. Counterparts. This Agreement, and any amendments hereto, and any Study Specific Work Order may be executed in any number of counterparts, and by facsimile or PDF

signatures, each of which counterparts will be deemed an original, and all of which will together constitute one and the same instrument.

13.2. Assignment. This Agreement, and any amendments hereto, and any Study Specific Work Order will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns each of which such successors and permitted assigns will be deemed to be a Party hereto and thereto for all purposes hereof. No Party may assign, delegate or otherwise transfer either this Agreement or any Study Specific Work Order, or any of its rights, interests or obligations hereunder or thereunder, without the prior written approval of the other Parties (with Norton acting for NCMG and the University acting for ULRF), and any attempt to do so will be null and void.

13.3. Governing Law. This Agreement and any Study Specific Work Orders shall be construed by and enforced under the laws of the Commonwealth of Kentucky (without regard to the conflict-of-laws principles thereof).

13.4. Amendments and Waivers. No amendment or waiver of any provision of this Agreement or any Study Specific Work Order will be valid and binding unless it is in writing and signed, in the case of an amendment, by Norton (for itself and on behalf of NCMG) and the University (for itself and on behalf of ULRF), or in the case of a waiver, by the Party (or in the case of NCMG, Norton) against whom the waiver is to be effective. No waiver by any Party of any breach or violation of, default under or inaccuracy in any representation, warranty or covenant hereunder or thereunder, whether intentional or not, will be deemed to extend to any prior or subsequent breach or violation of, default under, or inaccuracy in, any such representation, warranty or covenant hereunder or thereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence. No delay or omission on the part of any Party in exercising any right, power or remedy under this Agreement or any Study Specific Work Order will operate as a waiver hereof or thereof.

13.5. Entire Agreement. This Agreement and all schedules, exhibits, and attachments hereto, each Study Specific Work Order, the Clinical Affiliation Agreement, including each of the Supplemental Agreements attached thereto, and each of their respective schedules, exhibits, and attachments, the Academic Affiliation Agreement, and the Integration Agreement, constitutes the entire agreement of the Parties with respect to the subject matter thereof and supersedes and replaces any previous agreements relating to the same subject matter applicable to each Party, including without limitation the Terminating Agreements (as defined in the Academic Affiliation Agreement), but excluding the Surviving Agreements (as defined in the Academic Affiliation Agreement), which will survive and continue in accordance with their terms.

13.6. Notices. All notices, requests, approvals, demands, and other communications required or permitted to be given under this Agreement or any Study Specific Work Order will be in writing and will be deemed to have been duly given and to be effective when delivered personally (including delivery by express or courier service) or, if mailed, upon receipt demonstrated by a signed delivery receipt or a tracking report. Notices shall be addressed as follows or to such other address as either Party may designate by notice to the other Parties:

If to the Norton Parties:

Norton Hospitals, Inc.
Attn: President
4967 U.S. Highway 42, Suite 100
Louisville, KY 40222

With copies to:
Norton Hospitals, Inc.
Attn: Chief Legal Officer
4967 U.S. Highway 42, Suite 101
Louisville, KY 40222

If to the University Parties:

The University of Louisville
Attn: Executive Vice President for Research and Innovation
Jouett Hall
Louisville, KY 40292

With copies to:
Attn: Dean of the Medical School
323 East Chestnut
Louisville, KY 40292

Office of University Counsel
Attn: Thomas A. Hoy, General Counsel
206 Grawemeyer Hall
Louisville, KY 40292

13.7. Further Assurances. Each of the Parties shall execute and deliver such further instruments and take such other action as reasonably may be necessary to further effectuate the purposes and goals of this Agreement or any Study Specific Work Order, including correction of errata therein.

13.8. Compliance. Per Section 6.4.4, in the performance of their obligations under this Agreement and each Study Specific Work Order, the Parties will comply with all applicable laws and regulations, and will cooperate with each other to assess and assure such compliance as outlined in Article 6. Without limiting the generality of the foregoing, the Parties will observe and comply with the federal anti-kickback statute, set forth at 42 U.S.C. § 1320a-7b(b), and the federal prohibition against physician self-referrals, set forth at 42 U.S.C. § 1395nn in addition to the requirements set forth in Article 6. Notwithstanding anything to the contrary herein, all payments associated with this Agreement and each Study Specific Work Order are intended to comply with the requirements of applicable Kentucky state laws and the regulations promulgated thereunder.

13.9. Independent Contractor Relationship. The relationship between each of the Norton Parties (and their personnel), on the one hand, and the University Parties (and their personnel), on the other hand, will at all times be that of independent contracting parties. Each Party, and each

Party's respective personnel, will therefore be liable for their own respective debts, obligations, acts, and omissions, including the payment of all required withholding, social security, and other taxes. All salaries, wages, benefits, taxes, and other expenses of any kind relating to each Party's personnel will remain the sole responsibility of that Party.

13.10. Survival. The termination or expiration of this Agreement or any Study Specific Work Order for any reason will not affect the accrued rights or obligations of any Party under this Agreement and/or Study Specific Work Order(s) that by its terms is intended to survive such termination or expiration.

13.11. Severability. If any provision of this Agreement or any Study Specific Work Order will for any reason be held to be invalid or unenforceable, such invalidity or unenforceability will not affect any other provision of this Agreement and/or Study Specific Work Order(s), and this Agreement and/or Study Specific Work Order(s) will be construed as if such invalid or unenforceable provision were omitted.

13.12. Interpretation. The headings contained in this Agreement, or any Study Specific Work Order, or in any exhibit, schedule, or attachment and in the table of contents to this Agreement or any Study Specific Work Order, are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement and/or Study Specific Work Order(s). Except when the context otherwise requires, references to sections, articles, exhibits or schedules refer to sections, articles, exhibits or schedules of this Agreement. All exhibits and schedules annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized term used in any schedule or exhibit, but not otherwise defined therein, shall have the meaning ascribed to such term in this Agreement. Whenever used in this Agreement or any Study Specific Work Order, a singular number shall include the plural and a plural the singular. Pronouns of one gender shall include all genders. The words "hereof," "herein," and terms of similar import shall refer to this entire Agreement and/or the applicable Study Specific Work Order(s). Unless the context clearly requires otherwise, the use of the terms "including," "included," "such as," or terms of similar meaning, shall not be construed to imply the exclusion of any other particular elements and shall be deemed to be followed by the words "without limitation." References to a Person are also to its permitted successors and assigns.

13.13. Third-Party Beneficiaries. This Agreement is not intended, and will not be deemed or construed, to confer upon any Person, other than the Parties hereto, any right or interest, including without limiting the generality of the foregoing, any third-party beneficiary status or any right to enforce any provision of this Agreement or any Study Specific Work Order.

13.14. Strict Compliance. No failure by any Party to insist upon the strict performance of any obligation under this Agreement or any Study Specific Work Order will constitute a waiver of any breach thereof.

13.15. Authority. Each Party represents to the other that there is no limitation on its ability to enter into this Agreement or any Study Specific Work Order and carry out their respective obligations.

13.16. Attorneys. The Parties acknowledge that this Agreement has been negotiated and prepared by legal counsel on behalf of the University Parties and the Norton Parties. The Parties acknowledge that they have been advised of their right and have had the opportunity to have legal counsel represent them in their review and negotiation of the terms of this Agreement. The Parties acknowledge that (a) they have read and understand this Agreement and they are fully aware of its legal effect, (b) they are entering into this Agreement freely and voluntarily, and based on each Party's own judgment and not on any representations or promises made by the other Party, other than those contained in this Agreement, and (c) interpretation of this Agreement is to be construed as though the Parties jointly drafted the documents with the advice of legal counsel regardless of which Party actually drafted the document and, as such, the Agreement shall not be construed against any Party.

13.17. Confidentiality. Each of the University Parties and the Norton Parties shall, and shall use their best efforts to cause their officers, directors, employees, accountants, attorneys and other agents and Representatives to, hold in confidence all financial information, information regarding markets, marketing methods, valuation, valuation methods, compensation, compensation methods, sources or third-party payments, patient list and Patient Information and other proprietary information concerning the University or its Affiliates or Norton or its Affiliates ("**Confidential Information**"), with the exception of information that (a) comes into the public domain other than through a breach of this Agreement, (b) was in such Party's possession prior to disclosure by the other Party, (c) was generally known, by the receiving Party, at the time of disclosure, or becomes so generally known after such disclosure, through no act of the receiving Party, or (d) has come into the possession of the receiving Party from a third party who is not known by the receiving Party to be under any obligation to the disclosing Party to maintain the confidentiality of such information. In the event that a receiving Party is ordered to disclose a disclosing Party's Confidential Information pursuant to a judicial or governmental request, requirement, order, proceeding, audit or inspection, the receiving Party shall, to the extent legally permitted and practicable, provide the disclosing Party with prompt notice so that the disclosing Party may seek an appropriate protective order. If, in the absence of a protective order, the receiving Party is, on the advice of counsel, compelled as a matter of law to disclose any portion of the Confidential Information of the disclosing Party (including pursuant to the Kentucky Open Records Act ("KORA") (KRS § 61.870 – KRS § 61.884), the receiving Party may disclose only the portion of the Confidential Information that is required by law to be disclosed (prior to such disclosure, the disclosing Party will, to the extent legally permitted and practicable, be advised and consulted as to such disclosure and the nature and wording of such disclosure), and, with the exception of disclosures under KORA, each Party will use its reasonable best efforts to obtain confidential treatment for such Confidential Information. Nothing in this Section 13.17 shall limit the Parties' ability to use and disclose Confidential Information to enforce any right or remedy relating to this Agreement or any Study Specific Work Order.

IN WITNESS WHEREOF, the Parties hereto have signed this Agreement as of the Effective Date.

NORTON HOSPITALS, INC. dba NORTON CHILDREN'S HOSPITAL	NORTON CHILDREN'S MEDICAL GROUP, LLC
By:_____	By:_____
Name:_____	Name:_____
Title:_____	Title:_____
THE UNIVERSITY OF LOUISVILLE	UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION
By:_____	By:_____
Name:_____	Name:_____
Title:_____	Title:_____

Exhibit A – Example Form Study Specific Work Order

[*See attached*]

Title of Study: Protocol Number:

This Study Specific Work Order ("**Work Order**") is effective as of the date given below, among Norton Hospitals, Inc., dba Norton Children's Hospital ("**Norton**"), Norton Children's Medical Group, LLC ("**NCMG**" and, collectively with Norton, the "**Norton Parties**"), The University of Louisville (the "**University**"), acting on behalf of the University of Louisville School of Medicine (the "**Medical School**"), a component of the University, and University of Louisville Research Foundation ("**ULRF**" and, collectively with the University, the "**University Parties**"). The Norton Parties and the University Parties are collectively referred to herein as the "**Parties**" and individually as a "**Party**."

1. BACKGROUND

The Norton Parties and the University Parties are parties to Master Research Affiliation Agreement as of the Effective Date, as defined therein (the "**Research Agreement**"). Under the Research Agreement, the Parties are executing this Work Order to contract for the provision of certain services (the "**Research Services**") by the Norton Parties for the following Study.

2. THE STUDY

The Norton Parties agree to provide those Research Services described herein for the Study described below.

Study Title_____ **Protocol Number**_____ **Investigator's Name**_____ **Study Sponsor**_____

[1] The provisions herein shall be supplemented by, at a minimum, the following, as applicable:

1. Research Services costs
2. Access afforded to those contracted by the University to work on a Study, including collaborators that are not Pediatric Faculty
3. Data use ownership and entering into data use agreements
4. Equipment / maintenance of equipment
5. Retaining / use of biological samples
6. Intellectual property
7. IRB review
8. Monitoring
9. Costs related to Study injury
10. Clinical trials registration with clinicaltrials.gov

Initial Enrollment Maximum; Children's	**Subjects**
Total Enrollment Target; All Study Sites	**Subjects**
Children's Tax ID Number	
Effective Date of Work Order	

3. PERFORMANCE OF STUDY

a. Study Conduct. The University Parties, the Pediatric Faculty member serving as the principal investigator (the "**Investigator**"), and the Norton Parties agree to conduct the Study in strict accordance with the Study protocol ("**Protocol**") attached hereto as Appendix A (as it may be amended from time to time by the Sponsor), all applicable federal, state and local laws, regulations and guidelines relevant to the conduct of clinical protocols, conditions imposed by the IRB of record, any written instructions of the Sponsor relative to the Protocol's administration and the Research Agreement.

b. [Investigational Product. [Name of Investigational Product] (the "**Investigational Product**") and all other materials supplied under the Protocol shall be used by the Parties and Investigator only as specified in the Protocol. The Parties and Investigator agree to (a) handle and store the Investigational Product as specified in the Protocol or by Sponsor, (b) maintain records on use and disposition of the Investigational Product, and (c) dispose of the Investigational Product at the end of the Study according to Sponsor's instructions.] [Include if applicable].

c. [Study Data. Insert provisions relating to transfer of Study data between the Parties, if applicable.]

4. RESEARCH SERVICES

The specific services and items purchased are set forth in Appendix B hereto.

5. REPORTING

The Norton Parties shall provide the following reports required by Sponsor in addition to any reports required by the Research Agreement:

[*Fill in with reports*]

6. INVESTIGATOR

In the event that the Investigator becomes unable to perform any of the activities in the Study or to complete the Study for any reason, the Parties may provide a substitute Investigator, subject to the approval of the SPRC, in which case this Work Order shall continue in full force and

effect. If the SPRC in its reasonable discretion does not approve of the replacement Investigator, the matter shall be resolved by the PRC Leadership.

7. [COMPENSATION; EXPENSES]

a. Payment for Research Services. The University Parties shall pay the Norton Parties for those services actually provided by the Norton Parties that are identified as Research Services that may be billed to the University Parties in Appendix C at the rates set forth in Appendix C, provided Sponsor pays University Parties for those services.

b. Invoicing. Payments by the Norton Parties shall be sent to Norton at the following address:

Norton Hospitals, Inc.
4967 U.S. Highway 42, Suite 100
Louisville, KY 40222
Attn: _____

Norton's federal tax identification number is_____.

c. Payment from Third Party Payors. The Norton Parties shall not submit claims to, or otherwise seek reimbursement from, Medicare, Medicaid or any other Third Party Payor, whether public or private, for any costs covered by payments made by the University Parties under this Work Order.

8. ADDITIONAL COMPLIANCE REQUIREMENTS

If the Study is federally funded, in whole or in part, the Parties must comply with the additional terms of the award attached hereto to the extent applicable to such Party's performance hereunder.

9. TERM; TERMINATION

This Work Order shall continue until the Study is completed and all monies owed by the University Parties to the Norton Parties are paid in full or until terminated as provided in the Research Agreement.

10. INCORPORATION BY REFERENCE

The terms and conditions of the Research Agreement, Sponsor award agreement, any applicable subcontracts and Protocol, as approved by the Parties, Investigator, and the IRB (along with any subsequently approved amendments to the Research Agreement and/or Protocol), are hereby incorporated by reference into and made part of this Work Order. All defined terms in the Research Agreement shall have the same meaning when used in this Work Order.

11. NOTICES

Notices applicable to this Work Order shall be sent to:

If to the Norton Parties:	Norton Hospitals, Inc. Attn: _____ 4967 U.S. Highway 42, Suite 100 Louisville, KY 40222 With copies to: Norton Hospitals, Inc. Attn: Chief Legal Officer 4967 U.S. Highway 42, Suite 101 Louisville, KY 40222
If to the University Parties:	The University of Louisville Attn: Office of Sponsored Programs Administration 300 E. Market Street, Suite 300 Louisville, KY 40202 With copies to: Office of University Counsel Attn: Research Counsel 206 Grawemeyer Hall Louisville, KY 40292

12. ENTIRE AGREEMENT

This Work Order (including the Research Agreement) represents the entire and integrated agreement between the Parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding the Study.

NORTON HOSPITALS, INC. dba NORTON CHILDREN'S HOSPITAL

By:_____
Name:_____
Title:_____
Date:_____

NORTON CHILDREN'S MEDICAL GROUP, LLC

By:_____
Name:_____
Title:_____
Date:_____

THE UNIVERSITY OF LOUISVILLE

By:_____
Name:_____
Title:_____
Date:_____

UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION

By:_____
Name:_____
Title:_____
Date:_____