# AGREEMENT TO ESTABLISH THE CARE CONSORTIUM AND RESEARCH COLLABORATION

This AGREEMENT TO ESTABLISH THE CARE CONSORTIUM AND RESEARCH COLLABORATION ("Agreement") effective as of the date of the last signature below ("Effective Date") is entered into by and among The Methodist Hospital Research Institute ("TMHRI"), Cornell University for and on behalf of its Joan & Sanford I. Weill Medical College ("WCMC"), The New York and Presbyterian Hospital ("NYPH"), Emory University ("Emory"), University of Utah ("Utah"), and Thomas Jefferson University ("TJU"). TMHRI, WCMC, NYPH, Emory, Utah, and TJU are hereafter referred to respectively as a "Party" or the "Parties." For purposes of clarity, WCMC and NYPH are collectively one Party to this Agreement.

## RECITALS

WHEREAS, each of the Parties conducts research and is committed to advancing translational and clinical cancer research; and

WHEREAS, the Parties desire to establish a consortium to coordinate and collaborate on investigator-initiated research trials related to cancer; and

WHEREAS, this Agreement sets forth the principals that will govern such consortium.

**NOW THEREFORE**, in view of the foregoing recitals and in consideration of their mutual covenants herein, the Parties agree to the terms and conditions set forth below.

## Article 1. PURPOSE AND SCOPE OF THE CONSORTIUM

This Agreement establishes the terms of collaboration among the Parties to support the establishment of CARE: Consortium for the Advancement of Research Excellence (the "Consortium"). The Consortium will be comprised of a group of clinical and laboratory investigators who are employees of the Parties with the primary objective of conducting translational research studies incorporating innovative molecular diagnostics, targeted theraputic interventions and utilization of advanced statistical design. Each Party will appoint one researcher to this Consortium (each, a "Principal Investigator"). The Consortium's goal is to expedite the translation of laboratory research into the clinic and to develop a model for the implementation of effective personalized therapy. The Consortium will work closely with the pharmaceutical industry, the National Cancer Institute, and other federal, state, and private agencies and advocacy organizations.

# Article 2. ORGANIZATION AND OPERATION OF THE CONSORTIUM

2.1 <u>Organizational Structure</u>. Each Party will maintain its own organizational structure. The Consortium will not be a legal entity, but shall be an operating alliance with those involved in the Consortium remaining employees of their home institution.

- 2.2 Steering Committee. The structure of the Consortium shall include a steering committee with equal membership from each Party. The initial members shall be the Principal Investigators of each Party. A Party may not change its Principal Investigator unless approved by the steering committee, such approval to not be unreasonably withheld or delayed. In addition, if a Principal Investigator is no longer employed by a Party, the steering committee will allow such Party to replace its Principal Investigator, subject to approval by the steering committee. Other members of the steering committee may be appointed by mutual agreement of the steering committee The steering committee members shall have the following responsibilities: (1) promote research collaboration through the Consortium; (2) act as principal contacts for the Consortium; (3) plan and coordinate the activities of the Consortium within their respective institutions; (4) approve any fundraising, marketing, or commercial activities of the Consortium, taking into consideration each Party's own internal policies, which may require consent from a Party's executive officer or his or her designee; (5) periodically review and evaluate activities; (6) work out new ideas and strategic plans for the Consortium; (7) develop scientific guidelines and parameters for Consortium activities; and (8) advise the Parties on any recommended changes to the Consortium or this Agreement. The steering committee shall meet every other month, unless otherwise decided by the steering committee.
- 2.3 <u>Scientific Review Board</u>. The steering committee shall create a Scientific Review Board (the "<u>Review Board</u>"). The Review Board shall be comprised of equal membership of the Parties, and membership will consist of the Principal Investigators. The Review Board must review and approve any research study to be conducted under the Consortium (each, a "<u>Consortium Study</u>"). A majority vote is required for approval of a Consortium Study. If the Principal Investigator of an individual Party does not want, or is unable, to participate in any specific Consortium Study, then he or she may decline to participate and the other Parties may proceed separately, but under the auspices of this Agreement.

## Article 3. FACULTY AND PERSONNEL

Each Party shall be solely responsible for its own faculty and personnel, including but not limited to the payment or provision of any and all salary, compensation, benefits or other compensation, and shall not be responsible for any other Party's faculty or personnel. Each Party's faculty and personnel shall be subject only to their home institution's bylaws, policies, and procedures including policies related to human subject or animal research, patents, copyright, research misconduct, and conflicts of interest. Responsibility for assuring compliance with applicable federal, state, and local laws and regulations governing each Consortium Study shall be each Party's responsibility for its Principal Investigator and other employees, students, faculty or other study personnel performing the Consortium Study for each Party. Without limiting the preceding, each Party agrees that it will perform its obligations hereunder and conduct each Consortium Study in compliance with all applicable laws. In the event a Party becomes aware or receives notice of an investigation by a regulatory or funding agency of a Consortium Study, that Party will, to the extent permitted by law, promptly notify the other Parties and all of the applicable Parties will work together in good faith in response to such investigation.

## Article 4. TRADEMARKS

Directly, or through an affiliate, TMHRI has applied for registration of marks related to the name of the Consortium (the "Consortium Mark"). TMHRI hereby grants to each of the other Parties a non-exclusive, royalty-free license for the duration of this Agreement to use the Consortium Mark solely to identify that Party's participation in the Consortium. Before any Party engages in any marketing, promotion, or advertising of or related to the Consortium, that Party shall coordinate with the steering committee to develop mutually agreed upon marketing materials.

Each Party hereby grants to each other Party a non-exlusive, royalty-free license for the duration of this Agreement or a Consortium Study, whichever is longer, to use its name when (i) using the Consortium Mark as provided under this Agreement, provied that such use is solely to identify it as a participant in the Consortium, and (ii) to identify a Party on <a href="www.clinicaltrials.gov">www.clinicaltrials.gov</a> as a participant in a Consortium Study.

Except as otherwise expressly provided herein or with the express written approval of the applicable Party, no Party shall use any of the other Parties' names, logos, trademarks, service marks or other protected marks in advertising, promotions, or any publicity, press release or other public announcement, written or verbal, unless required by law.

#### Article 5. INVENTIONS

Ownership of intellectual property conceived during a Consortium Study shall be determined in accordance with the laws of the United States of America and, to the extent not in conflict therewith, the policies and procedures regarding intellectual property of the employer(s) of the inventor(s), author(s) and creator(s). Nothing in this Agreement shall create or imply a license by any Party to any other Party of any technology used during or conceived in connection with a Consortium Study, unless set forth in an agreement for a Consortium Study. Each Party shall retain all right, title and interest in any patent, patent applications, trade secret, know-how and other intellectual property that was owned by such Party prior to the date of signing of this Agreement and no license, grant or assignment, express or implied, by estoppel or otherwise, with regard thereto is intended by, or shall be inferrred from, this Agreement.

#### Article 6. CONFIDENTIAL INFORMATION

As part of each Party's participation in the development of the Consortium, each Party (as a recipient of Confidential Information, the "Receiving Party") acknowledges that information it acquires from the other Parties (each as a provider of Confidential Information, the "Disclosing Party") for use in connection with a Consortium Study that is treated as confidential or proprietary by the Disclosing Party shall be "Confidential Information". Confidential Information may include but is not limited to patient information, financial information, unpublished data, or terms of agreements with third parties related to any of the foregoing.

Having acknowledged the foregoing, the Receiving Party agrees: (a) to exercise the same degree of care (but no less than a reasonable degree of care) that Receiving Party uses to protect its own Confidential Information; and (b) not to, directly or indirectly, disclose, copy, transfer or allow

access to any Confidential Information of the Disclosing Party to any third party, and not to use the Disclosing Party's Confidential Information except as provided by this Agreement. Confidential Information shall not include information which:

- (i) is lawfully in the possession of the Receiving Party prior to disclosure by the Disclosing Party,
- (ii) is or becomes generally available to the public through no breach of this Agreement by the Receiving Party or its agents,
- (iii) become available to the Receiving Party on a non-confidential basis from a source, other than the Disclosing Party or its agents, who is not prohibited by a contractual, legal or fiduciary obligation from disclosing such portions of the Confidential Information to Receiving Party;
- (iv) the Receiving Party can demonstrate by written records was developed by the Receiving Party independently of its knowledge of or access to the Disclosing Party's Confidential Information; or
- (v) is published in accordance with this Agreement.

Notwithstanding anything to the contrary herein, (x) the Receiving Party may disclose Confidential Information to its employees and to third parties performing services for the Receiving Party that are related to the purposes of this Agreement and that have need to know, and are subject to confidentiality considerations no less stringent than those in this Agreement, and (y) the Receiving Party may retain Confidential Information that is included in its electronic backups or archives in the normal course of its business, regardless of any requirements under this Agreement to return or destroy Confidential Information, provided such backups and archives are maintained as confidential.

If the Receiving Party is required to disclose any of the Confidential Information under any applicable law, regulation, court order or other judicial or regulatory action, the Receiving Party, may do so, provided that it shall use its reasonable efforts under the circumstances to provide the Disclosing Party with prompt notice, unless notice is prohibited by law, court order or regulation, so that the Disclosing Party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement. The Receiving Party shall use reasonable efforts to furnish only that portion of the Confidential Information which it is required to furnish under the applicable requirement. Additionally, Confidential Information (i) will otherwise remain subject to all terms and conditions of this Agreement and (ii) will not lose its confidential status for other purposes through such disclosure.

The Confidential Information terms and obligations in this Agreement shall survive for five (5) years from the expiration or termination of this Agreement. Upon request of Disclosing Party, Receiving Party shall return Confidential Information to Disclosing Party and/or destroy such Confidential Information and provide written certification of its destruction, provided Receiving Party may keep Confidential Information for legal archival purposes and it shall remain otherwise subject to the provisions of this Article 6.

## Article 7. RESEARCH GOVERNANCE

- Consortium Study shall be the lead investigator for the Consortium Study (the "Lead PI"), and the Lead PI's home institution shall be the coordinating center for that Consortium Study; the other Consortium members will be individual sites. The home institution of the Lead PI will hold the contract with the funding entity and will negotiate a per patient budget for the Consortium Study, and include a fee for coordinating site duties. The per patient budget will be the same for every Consortium institution. Each Party will bear its own expenses, except as may otherwise be set forth and agreed to in a Consortium Study agreement. Each Consortium Principal Investigator may choose to opt in or opt out of any particular Consortium Study. If a Principal Investigator chooses to opt in to a Consortium Study, that Principal Investigator's home institution will enter into a subcontract with the Lead PI's home institution. The form of the subcontract will be agreed upon by the Consortium members.
- 7.2 <u>Lead Institution's Obligations</u>. The home institution of the Lead PI will be responsible for data reporting, negotiations and communications with the funding entity, oversight of any Data Safety Monitoring Board (as applicable), approval of quality assurance and monitoring plans, regulatory filings, and Institutional Review Board (the "<u>IRB</u>") oversight. All sub-investigators will submit the required data (e.g., SAEs, deviations, etc.) to the coordinating site's IRB. In addition, each Party shall be responsible for monitoring the conduct of its own Principal Investigator and other research personnel participating in a Consortium Study and ensuring compliance with all applicable federal, state, and local laws and regulations.
- IRB Approval. If agreed by the Parties for each Consortium Study, the IRB of the Lead 7.3 PI's home institution will be the IRB of record for each Consortium Study ("Lead IRB"). If so agreed, each entity participating in a particular Consortium Study will have full reciprocity with the other entities' IRBs as noted on each institution's FWA, as appropriate, for each Consortium Study. The results of the Lead IRB's review of a Consortium Study protocol will be shared with the IRBs of the other Parties, and the Lead IRB will share the following documents and information with the other Parties' IRBs, as applicable: submitted and approved protocols, approved informed consent forms and HIPAA authorizations, adverse event reports, deviations, protocol amendments, minutes and correspondence of the Lead IRB (unless subject to applicable privilege), compliance or patient safety concerns, continuing reviews, and other items reasonably requested by a Party's IRB. The Lead IRB will review and approve each Consortium Study in accordance with applicable laws. A Party's IRB can disapprove a Consortium Study that has been approved by the Lead IRB in which instance, that Principal Investigator will not participate in that specific Consortium Study. No research will begin until appropriate IRB approval is finalized.

In the event that an institution participating in a particular Consortium Study does not want to rely on the Lead IRB, then that Party will utilize its own IRB and will submit information and documents to the Lead IRB in accordance with applicable laws including, but not limited to, submitted and approved protocols, approved informed consent forms and HIPAA authorizations, adverse event reports, deviations, protocol amendments, minutes and correspondence of the entity IRB (unless subject to applicable privilege), compliance or patient safety concerns,

continuing reviews, and other items reasonably requested by the Lead IRB. The institution IRB will review and approve the applicable Consortium Study in accordance with applicable law, and no research will begin at that institution until both the institution's IRB and the Lead IRB have approved the Consortium Study.

- 7.4 <u>Biosafety Committee Approval</u>. If Biosafety Committee approval is needed for a Consortium Study, each Principal Investigator will seek approval from his or her home institution's Biosafety Committee. If Biosafety Committee approval is required, work shall not begin until such time as all Biosafety Committee requirements are fully met.
- 7.5 <u>Material Transfer Agreement ("MTA")</u>. If an MTA is needed to conduct a Consortium Study, the Lead PI shall initiate the MTA, unless otherwise agreed by the Parties.
- 7.6 <u>Conflicts of Interest</u>. Each Principal Investigator shall be subject to the policies and procedures concerning conflicts of interest of his/her home institution. Each Party shall be responsible for managing any such conflict of interest and shall inform the other Parties of the status of a conflict of interest of its Principal Investigator or other Consortium Study personnel as it pertains to any particular Consortium Study.
- Consortium Tissue Bank. The Consortium will establish a Consortium Tissue Bank. 7.7 Tissue collected as part of a Consortium Study will physically remain at each institution where it was collected, but will be marked as "Consortium Tissue Bank" and included in the Consortium Tissue Bank at each home institution. Each Party will separately bank, identify, and track the tissue it has donated to the Consortium Tissue Bank in accordance with its own banking protocols. The Consortium will create a tissue Resource Allocation Committee ("RAC") which will be responsible for maintaining a database and approving the use of all Consortium tissue for each Consortium Study. The RAC will appoint an individual at one of the Party institutions to develop and maintain the database for the Consortium Tissue Bank. The RAC will be comprised of each of the Consortium Principal Investigators and will meet on an ad hoc basis. Each Principal Investigator is responsible for obtaining appropriate subject authorization in accordance with the Health Insurance Portability and Accountability Act ("HIPAA") regulations and any applicable state law, and IRB approval, as necessary, to bank tissue into the Consortium Tissue Bank. A Principal Investigator can also request to use Consortium tissue for a non-Consortium Study, subject to the approval of the RAC. If a Party terminates this Agreement and withdraws from the Consortium, its tissue is "withdrawn" from the Consortium's virtual Consortium Tissue Bank. If no one requests to use a specific tissue sample in the Consortium Tissue Bank for a Consortium Study within three (3) years after clinical use of that tissue has stopped, the sample will revert back to the home institution. Tissue may be transferred among Consortium Principal Investigators through the Material Transfer Agreement, as set forth in Section 7.6 above.

# Article 8. PUBLICATIONS

All written publications and oral presentations of a Consortium Study shall comply with the recognized ethical standards concerning publications and authorship adopted by the publishing journal (e.g., the International Committee of Medical Journal Editors ("ICMJE") Uniform

Requirements for Manuscripts Submitted to Biomedical Journals) and/or the applicable funding agency, as well as the policies of the applicable Principal Investigator's home institution. For each Consortium Study, the Principal Investigators will make reasonable efforts to publish a joint publication with all participating Principal Investigators. The Lead PI for the Consortium Study will be responsible for drafting any joint publication, unless otherwise agreed by the other Principal Investigators. Each Party will have the right to review a joint manuscript prior to its publication. In the event there is no joint publication of any particular Consortium Study within twelve (12) months upon the completion of the Consortium Study at all sites, any Party or Principal Investigator who participated in that Consortium Study may publish his or her institution's results independently. Each such publication shall acknowlege that the research was conducted through the Consortium.

#### Article 9. CONSORTIUM DATA AND HIPAA

- 9.1 <u>Data Ownership</u>. Any data generated as part of a Consortium Study will belong to the Party whose Principal Investigator generated such data. Each Party gives the other Parties the right to use data generated in performance of a Consortium Study for their own academic, internal non-commercial research, and patient care use.
- 9.2 HIPAA. Each Party shall abide by all federal, state, and local laws pertaining to the privacy, security and confidentiality governing information or records obtained, generated, or reviewed in the course of conducting a Consortium Study. Each Party also acknowledges that it must protect and secure patient health information. As applicable, each Party and its Principal Investigator shall comply with HIPAA and with all other applicable federal or state laws governing patient confidentiality, and each Principal Investigator shall obtain all legally required authorizations needed to use or disclose such information or records for a Consortium Study. If in connection with a Consortium Study or the performance of this Agreement a Party and/or any of its respective agents, employees, officers, or representatives come into contact with individually identifiable health information relating to patients of a Party who are not Consortium Study subjects, the other Parties agree to, and agree to ensure their respective agents, employees, officers, or representatives agree to, maintain the confidentiality of such information and not to use it for any purpose. All subject/patient medical records shall remain the property of the Party treating that patient and the other Parties shall protect the identity of patient/subject as required by HIPAA, the consent document, and all applicable laws and regulations, and the Parites shall otherwise comply with all applicable laws and policies of an institution regarding the confidentiality of such records. Each Party also shall comply with the other Parties' applicable policies and procedures if a Principal Investigator wants to gain access to another Party's medical records and protected health information for a Consortium Study. Each Party's personnel on site at any premises of any other Party shall comply with all applicable policies and procedures of that Party, including but not limited to security, safety, infection control and patient privacy.

## Article 10. COSTS AND EXPENSES

Any and all costs, expenses or liabilities of any Party arising out of its participation in this Agreement and the development of the Consortium shall be borne by each Party individually. No Party shall be liable or obligated to the other Parties for any such cost, expense, nor liability.

## Article 11. TERM AND TERMINATION

This Agreement shall commence on the Effective Date and remain in force for a period of five (5) years. Each Party reserves the right to terminate its participation under this Agreement at any time for any reason with thirty (30) days prior written notice to the other Parties. Any Party may terminate this Agreement immediately upon written notice to the other Parties to protect the health and safety of Consortium Study subjects. Termination of this Agreement by a Party will result in the withdrawl of participation of any Consortium Study by that terminating Party's Principal Investigator. In the event of termination by one or more but less than all Parties, this Agreement will remain in full force and effect with respect to the remaining Parties.

# Article 12. INDEPENDENT CONTRACTORS

The Parties agree that at all times during the term of this Agreement each is an independent contractor to the others and that this Agreement does not create any relationship other than that of independent contractors, including any partnership, agency, or joint venture.

# Article 13. ENTIRE AGREEMENT, AMENDMENT, WAIVER, SEVERABILITY

This Agreement sets forth the entire agreement and understanding of the Parties relating to its subject matter, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to its subject matter. Any changes to this Agreement shall be in writing in the form of an amendment mutually agreed upon and duly executed by all of the Parties. This Agreement may be executed in one or more counterparts, each of which when executed and delivered will be deemed to be an original, but all of which taken together will constitute one and the same agreement. This Agreement will become effective when counterparts have been signed by each of the Parties and delivered by email or other means to each other Party. The waiver of any breach of any term or condition of this Agreement shall not be deemed to constitute the waiver of any other breach of the same or any other term or condition. The invalidity or unenforceability of any provision or portion of any provision of this Agreement shall not affect the validity or enforceability of the remainder of the same provision or any other provision of this Agreement and each provision hereof or portion of such shall be enforced to the fullest extent permitted by The following sections shall survive expiration or termination of this applicable law. Agreement: 3, 4, 5, 6, 8, 9, and 16.

## Article 14. NONEXCLUSIVITY

This Agreement is not exclusive. The Parties will be able to collaborate freely with other institutions or entities.

# Article 15. NOTICES

All notices, requests, or demands to be given by a Party to the other Parties under the provisions of this Agreement will be forwarded by certified mail return receipt requested, or personally delivered to the respective Parties as follows:

TMHRI 6565 Fannin, R2-216 Houston, Texas 77030 Attn: COO Emory University Office of Sponsored Programs 1599 Clifton Rd NE, 4<sup>th</sup> Floor Mailstop: 1599-001-1BA Atlanta, GA 30322

Attn: Director, Contracts Administration

Thomas Jefferson University
Office of Research Administration
125 S. 9<sup>th</sup> Street
Second Floor Sheridan
Philadelphia, PA 19107
Attn: Director, Research Administration

Weill Medical College of Cornell University Joint Clinical Trials Office 1300 York Avenue, Box 305 New York, NY 10065

The New York and Presbyterian Hospital Joint Clinical Trials Office 1300 York Avenue, Box 305 New York, NY 10065

University of Utah Attn: Director, Office of Sponsored Projects 75 South 2000 East, RAB Rm. 211 Salt Lake City, UT 84112

or at such other address or addresses as any Party may from time to time designate by written notice to the other Parties.

#### Article 16. RESPONSIBILITY FOR RISK AND INSURANCE

- 16.1 <u>Responsibility for Risk</u>. The Parties are separate and independent entities, and no Party is an agent of another Party. Each Party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors to the extent allowed by law.
- 16.2 <u>Insurance</u>. Each Party shall maintain at all times a policy or policies of insurance in commercially reasonable amounts to provide comprehensive coverage for its activities under this Agreement and and Consortium Study. Any such insurance may be through programs of self insurance.

#### Article 17. REGULATORY COMPLIANCE

Each Party agrees that it shall at all times conduct itself in compliance with all applicable federal, state and local laws, rules and regulations in connection with the performance of this Agreement. It is not the purpose, nor is it a requirement of this Agreement or of any other agreement between or among the Parties to offer or receive any remuneration or inducement to encourage the referral of any patient or other health care business. Each Party to this Agreement represents and agrees that it shall not knowingly violate the Anti-Kickback Statute and the Stark law with respect to the performance of this Agreement.

# Article 18. ASSIGNMENT

The provisions of this Agreement are for the benefit of the Parties and not for any other person or entity. Because this Agreement is personal to the Parties, it shall not be assignable or otherwise transferable in whole or in part, voluntarily, involuntarily or by operation of law including any merger or consolidation, substantial change in ownership or control of an Institution's business, or any other means, without the prior written approval of the other Parties. Except for the rights expressly granted herein, nothing in this Agreement shall be constured as conferring upon any Party by implicaton, estoppel or otherwise any additional rights, including but not limited to, any additional rights in or to confidential information, intellectual property or inventions of other parties.

## Article 19. INTERPRETATION

The Parties acknowledge that each Party has reviewed and revised, and has been given the opportunity to review and revise, this Agreement and that the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement or any amendments or Exhibits thereto.

#### Article 20. EXPORT CONTROLS

This Agreement is made subject to the laws and regulations concerning the export and re-export of products, services or technical information that the U.S. government may impose from time to time, and to the exceptions thereunder. Each Party shall comply with export controls to the extent applicable.

[Signature page to follow.]

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Emory University	University of Utah
Ву:	By: Bush
Name:	Name, Brent, K. Brown, Esq.
Title;	Title: Dir., Office of Sponsored Projects
Date:	Date: 1/23/15

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Cornell University for and on behalf of its Joan and Sanford I, Weill Medical College	The New York and Presbyterian Hospital
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Emory University	University of Utah
By: huld)	Ву:
Name: Iruka A. Ndubuizu, LLM	Name:
Title: Asst. Director, OSP	Title:
Date: February 16, 2015	Date: