North American Consortium for Histiocytosis

NACHO Operations Center | St. Jude Children's Research Hospital
262 Danny Thomas Place, MS 721 | Memphis, TN 38105
www.nacho-consortium.org

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Thank you for your interest in joining NACHO. Please review the information below prior to submitting an application for Associate Membership.

NACHO Master Consortium Agreement

- Membership will only be granted to institutions that execute a Master Consortium Agreement with St. Jude Children's Research Hospital in its role as the legal entity and Operations Center for NACHO.
- **The agreement must be accepted by your institution as presented unless provisions in it violate your institution's state law or organization policy; no exceptions can be made**.
- Applicants should share the Master Consortium Agreement with the appropriate legal department representative and obtain signature from a legal signing entity as soon as possible.

All institutions interested in NACHO membership must meet the criteria listed below (please see the website for a compete list).

- Have an investigator with clinical trials experience who has the availability and desire to act as a PI for that institution.
- Demonstrate and/or have evidence of the infrastructure necessary to perform clinical studies.
- Be committed to prioritizing NACHO protocols and to providing complete and timely data, including follow-up information. It is understood that this does not prohibit members from engaging in other research activities.
- Be willing and able to comply with: a NACHO clinical trials audits at least once every three (3) years; Federal Drug Administration (FDA) requirements and/or other local, regional, state, and national government regulations, as applicable, for conduct of clinical trials; and NACHO regulatory requirements and SOPs.

Associate Member Investigators

- Each institution must identify one Principal Investigator and one Alternate Principal Investigator who will be responsible for NACHO activities at the institution including:
    - Directly supervising the performance and administration of NACHO clinical trials, ensuring compliance with protocol documents and identifying investigators and personnel to ensure timely and efficient work.
    - Circulating information about and from NACHO to all pertinent personnel.

Clinical Studies and Riders

- Execution of a Study Rider is required for each NACHO study opened at an institution.
- NACHO studies are coordinated through various NACHO Full Member Institutions.
- Protocol files will only be distributed once membership is approved by the NACHO Executive Board and a Master Consortium Agreement is executed between the institution and St. Jude Children's Research Hospital on behalf of NACHO.

Funding

- Member institutions registering patients on the LCH-IV and/or LCH-CLO studies will be eligible to receive reimbursement for expenses associated with enrollment (subject to availability).
- Funds from the St. Baldrick's Foundation Consortium Grant are designated only for Full Member Institutions.

Questions

- If you have questions about applying for Associate Membership, please contact Beth Anne Miller at bethanne.miller@st.jude.org or 901-595-6873.

CONSORTIUM AGREEMENT

North American Consortium for Histiocytosis (NACHO)

This Consortium Agreement ("Agreement") effective as of **February 17, 2016** ("Effective Date") is by and between the NACHO Participating Site signatory **("Consortium Member")** and **ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC. ("St. Jude")**, located at 262 Danny Thomas Place, Memphis, Tennessee 38105.

The terms of this Agreement are binding on the NACHO Consortium institutions that sign this Consortium Agreement. In addition, each Consortium Member that wishes to participate in a NACHO Clinical Study Protocol will sign a Study-specific Clinical Study Protocol Rider attached as **Exhibit A** to this Agreement.

Individually each is a "Party" and collectively the "Parties."

RECITALS

WHEREAS, St. Jude Children's Research Hospital mission is to advance cures, and means of prevention, for pediatric catastrophic diseases through medical research and treatment; and

WHEREAS, St. Jude is the operations center of the North American Consortium for Histiocytosis under the direction of Carlos Rodriguez-Galindo, MD; and

WHEREAS, Consortium Member engages in research activities and services, including creation, implementation, and documentation of clinical research, testing, and trials through research study protocols approved by one or more Institutional Review Boards; and

WHEREAS, Consortium Member wishes to participate in North American Consortium for Histiocytosis Clinical Study Protocols from time to time, and the North American Consortium for Histiocytosis desires for Consortium Member to participate in Clinical Study Protocols on the terms and conditions set forth herein and in the Study agreements; and

WHEREAS, each Clinical Study Protocol will further the North American Consortium for Histiocytosis research objectives consistent with its mission; and

WHEREAS, Consortium Member has reviewed the Clinical Study Protocol Rider template attached hereto as **Exhibit A** and incorporated herein; and

WHEREAS, Consortium Member has facilities, personnel, and support sufficient to perform and adhere to the Study Protocol, the terms of this Agreement, and Good Clinical Practice Guidelines as set forth in Title 21 of the U.S. Code of Federal Regulations; and

WHEREAS, St. Jude has facilities, personnel, and support to coordinate the Clinical Study Protocol with the Consortium Member.

NOW, THEREFORE, in consideration of the promises and covenants contained herein, the Parties agree as follows:

Definitions:

Biological Samples: Diagnostic tests, data, and body fluids (e.g., blood, urine, saliva, sera), bone marrow, tumor samples, tissue, tissue biopsies, and biological samples and materials derived therefrom.

Clinical Study Protocol ("Study" or "Study Protocol"): Administered by the NACHO Operations Center; IRB approved NACHO Study and document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project according to the International Conference on Harmonization Good Clinical Practice guidelines. Attached by reference to the Rider as **Attachment A**.

Clinical Study Protocol Rider ("Rider"): Study-specific agreement as set out in a separate Rider substantially in the form of **Exhibit A** attached hereto and incorporated herein for each Study in which a Consortium Member will participate. NACHO shall implement a Clinical Study Protocol Rider in advance, and each Rider is incorporated and will be subject to the terms of this Agreement upon execution by both Consortium Member and NACHO.

Confidential Information: Includes but is not limited to trade secrets, know how, inventions, techniques, processes, programs, documentation, data, service manuals, technical reports, research, development, regulatory affairs, agreements, negotiations, financial information, scientific information, sales and marketing plans, and confidential information of a third party that is disclosed to NACHO, St. Jude, or its affiliates, and is in turn disclosed to Consortium Member by NACHO, St. Jude, or any of its affiliates, or is learned by Consortium Member, through visual or other inspection. Confidential Information may be in oral, written, graphic, pictorial, physical, computer-readable or any other form or medium. Confidential Information may, but will not necessarily, be marked "CONFIDENTIAL."

Consortium Member Site Investigator ("Site Investigator"): Consortium Member's designated Principal Investigator and his/her alternate investigator, co-investigators and sub-investigators, if any, who will coordinate Study Protocol activities at the Consortium Member institution, and with responsibilities in accordance with the terms and conditions of this Agreement.

North American Consortium for Histiocytosis ("NACHO"): First multi-institutional consortium in North America with a solid scientific agenda and the research infrastructure necessary for the development and effective implementation of clinical and translational studies and biological research for histiocytic diseases.

NACHO Executive Committee ("**EC"):** Governing body overseeing all NACHO Studies and Consortium Members' participation.

NACHO Operations Center: St. Jude is the operations center responsible for day-to-day management of NACHO and oversight of all its administrative responsibilities.

NACHO Principal Investigator ("NACHO PI"): Carlos Rodriguez-Galindo, MD.

NACHO Standard Operating Procedures ("**SOP"):** Procedures developed by NACHO, as amended and updated from time to time by the EC, and incorporated herein by reference. The NACHO Operations Center maintains, makes them available via www.nacho-consortium.org and will notify Consortium Member Site Investigators in writing of changes to the SOPs.

Participating Site: Consortium Member that participates in a Study Protocol according to the Study-specific Rider.

Performance Period: Begins on the Effective Date and continues as long as Consortium Member is a current and active NACHO member in good standing, or until earlier terminated at the conclusion of all activities in support of or relating to the Study Protocol.

Records: Complete and accurate written records, accounts, notes, reports, and case report forms for each Participant, and books, records, documents, and other evidence of accounting procedures and practices related to each Rider, sufficient to reflect properly all costs of whatever nature incurred for the performance of each Rider and consistent with contracts for funding a Study.

Research Personnel: Site Investigator, Consortium Member, and their respective employees, contractors, and agents involved with the Studies and Services to be performed hereunder.

Services: Activities performed in support of or relating to the Study Protocol.

Sponsor: St. Jude, or any government agency, philanthropic entity, individual donor, or corporation that funds a specific NACHO Study.

Sponsored Research: NACHO Study funded by a corporation and not a grant, or research using a proprietary Study Drug.

Sponsored Research Agreement: Written agreement between St. Jude and a Sponsor(s) who is a corporation providing funding and/or proprietary Study Drug.

Study Data: Accessioned Study Protocol data.

Study Subject ("Study Subject" or "Participant"): Participant who is enrolled on a NACHO Study.

1. Scope of Work.

1.1 St. Jude and Consortium Member Representations.

(a) St. Jude is responsible for the NACHO day-to-day management and oversight of all administrative responsibilities, including but not limited to: (i) administrative services, (ii) negotiating and executing clinical trial agreements with Sponsors, and (iii) complying with Sponsor requirements, including but not limited to expenditure reports, effort reports, and progress reports.

(b) During the term of this Agreement, neither St. Jude nor Consortium Member will enter into an agreement to provide services that prevent it from conducting a Study in which the Consortium Member is participating.

(c) Consortium Members agree to cooperate with one another, consistent with the terms and conditions of this Agreement, to continue the operation of NACHO for the purpose of supporting research related to histiocytic diseases.

(d) Consortium Members will abide by all NACHO SOPs.

(e) The Parties agree to use best efforts to resolve disputes in an informal manner. If the Parties are unable to resolve a dispute arising out of or in connection with this Agreement, Parties agree that such dispute will be resolved by the NACHO EC.

1.2 Study Protocol and Agreements. St. Jude and the Consortium Member shall undertake the implementation and performance of one or more Study Protocol(s) as may be amended from time to time by St. Jude on behalf of the Operations Center and as set out in a separate Rider substantially in the form of **Exhibit A** attached hereto and incorporated herein. The Rider will identify the Study Protocol by name and the Site Investigator. Studies performed under a Rider are subject to all applicable federal, state and local laws and regulations and the terms in this Agreement, and the Rider may also include additional terms and requirements that are specific to that Study Protocol and Sponsor Research Agreement. Each Rider will be incorporated by reference into and made part of this Agreement upon execution of such Rider. Any modification to an executed Rider must be made in writing, signed by each of the Parties to the Rider. In the event of a conflict between this Agreement and any Study Protocol, the terms of the Study Protocol will control with respect to scientific matters applicable to the Study Protocol to the extent that the Study Protocol also conforms to applicable laws, rules, regulations, and generally accepted standards of good clinical practice, and the terms of this Agreement will control for all other matters. In the event of a conflict between this Agreement and any Rider, the terms of this Agreement will control unless specifically identified as an additional term or deleted term/provision by such Rider and as specifically agreed to by the Parties to such Rider. Both Parties shall exercise their respective good faith efforts to carry out their responsibilities pursuant to the Study Protocol, Rider, and this Agreement. Each Party will be responsible for administering the Study Protocol and represents that it is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement. Consortium Member, under the direction of Site Investigator, will enter eligible participants onto a Study Protocol, and will

furnish timely data, specimens, and follow-up information to the NACHO Operations Center or other locations as outlined in the applicable Protocol.

1.3 Study Subject Informed Consent and Data Authorization. Prior to a participant's enrollment in the Study Protocol, the Consortium Member will obtain informed written consent to participate in the Study from the Study Subject, and authorization to disclose the Study Subject's health and personal data to St. Jude, NACHO, Sponsor, the FDA, and other health authorities and regulatory institutions as required, and will document the disclosure(s) pursuant to the requirements of the privacy rule issued under 45 C.F.R. Parts 160 & 164.

2. Term and Termination.

2.1 Term. This Agreement shall begin on the Effective Date and continue as long as Consortium Member has a current and active membership in good standing within NACHO, or until earlier terminated at the conclusion of all activities in support of or relating to the Study Protocol, in accordance with this Agreement. Participant recruitment into the Study Protocol and production of Study Data will proceed according to the Study Protocol and NACHO SOPs.

2.2 Consortium Member Termination. If a Consortium Member's membership is terminated, the Consortium Member shall fulfill and complete its obligations under and in accordance with the Rider and Study Protocol in which it is participating and this Agreement.

2.3 Termination with Notice by St. Jude. St. Jude may terminate this Agreement or the conduct of a Study Protocol without cause by written notice to the Consortium Member at least thirty (30) days prior to the termination date. The termination date will be the date specified in the notice, and is effective upon the Consortium Member's completion of all standing obligations to the Consortium and to any Study Protocol in which it is participating, as described in Section 2.6 of this Agreement.

2.4 Immediate Termination or Suspension by St. Jude for Cause. St. Jude may immediately and without penalty terminate this Agreement or the conduct of the Study Protocol, and terminate or suspend enrollment or randomization of Study Subjects upon written notice to Consortium Member if: (i) St. Jude or any Consortium Member has indication of a Study Subject suffering serious physical harm; (ii) St. Jude or any Consortium Member becomes aware of efficacy or safety information that could significantly affect or alter continuation of the Study Protocol; (iii) St. Jude terminates the Study Protocol in its sole discretion; (iv) Consortium Member has violated or is reasonably suspected of violating one or more laws, regulations, or the Study Protocol; or (v) Consortium Member has breached or is reasonably suspected of breaching one or more term or condition of this Agreement and fails to cure the breach within thirty (30) days of receiving written notice from St. Jude. The termination date will be the date specified in the notice and is effective upon the Consortium Member's completion of all standing obligations to the Consortium and to any Study Protocol in which it is participating, as described in Section 2.6 of this Agreement.

2.5 Termination for Change in Funding. Notwithstanding any other provisions of this Agreement, if the funds anticipated for the continued fulfillment of a Study or Services under a

Rider or this Agreement are at any time not forthcoming or a third-party funding agreement is terminated, then either Party may terminate this Agreement and Rider for a particular Study by giving thirty (30) days written notice to the other Party specifying the reasons for the termination. In such event, NACHO shall not be responsible for making payments to the Consortium Member for which it is itself not reimbursed by the funding source. NACHO or St. Jude may terminate this Agreement if the prime sponsor ceases or materially reduces its support of NACHO Study Protocols.

2.6 Effects of Termination. NACHO or St. Jude may terminate a Study Protocol and Rider, or this Agreement as defined in this Section 2. St. Jude will notify the Consortium Member through electronic or paper (if required by Consortium Member) mailing notifications in the event a Study Protocol is to be terminated. Upon termination of this Agreement or termination or suspension of the Study Protocol:

(a) This Agreement and all of the Parties' rights, obligations, liabilities, and responsibilities, except rights, obligations, liabilities, and responsibilities that expressly survive termination of this Agreement, will terminate upon completion of each Party's obligations hereunder.

(b) Unless otherwise directed by St. Jude, the Consortium Member agrees to continue active treatment of current participants to the extent medically permissible pursuant to the Study Protocol, continue long-term follow-up on all participants-to-date in accordance with the Study Protocol, and be subject to, and cooperate with, future audits. Following termination, Consortium Member will take all steps necessary for the protection, preservation, and identification of all participant information, continue to monitor Study Subjects as appropriate, and maintain Study Data as set forth in the Study Protocol and in accordance with good clinical practice guidelines. The Parties will negotiate continued monitoring and Study Data maintenance terms in good faith.

(c) St. Jude and Consortium Member will terminate or suspend enrollment as appropriate if enrollment or randomization of additional Study Subjects is terminated or suspended, and will continue to conduct the Study in accordance with the Study Protocol, Rider and this Agreement for Study Subjects then enrolled.

(d) Consortium Member will use its best efforts to promptly limit or terminate outstanding commitments, conclude the work contemplated under this Agreement and Rider, and not incur additional commitments. Final accounting and payments will be made in accordance with the Study Protocol and Rider.

3. Study Supervision; Site Investigators.

3.1 Site Investigator(s) and Research Personnel.

(a) Each Consortium Member will designate a Site Investigator. Site Investigators shall be licensed physicians and qualified by training and experience to conduct a Study pursuant to a clinical trial protocol and applicable laws and regulations. Consortium

Member shall notify St. Jude if the Site Investigator ceases to serve in that capacity, and will designate a replacement Site Investigator, subject to NACHO's approval in 3.1(c).

(b) A Site Investigator shall receive and be familiar with the Study Protocol and information relating to a Study drug. Each Site Investigator shall ensure that Study monitors at his or her Consortium Member institution are qualified by training and experience to monitor the progress of the Study Protocol (including safety monitoring and data monitoring) and to timely and accurately report Study Protocol activity in monitoring logs and reports, pursuant to all applicable laws and regulations.

(c) Consortium Member shall ensure that Site Investigator and Research Personnel who are involved in the conduct of the Study Protocol are appropriately trained by Consortium Member and if applicable, have completed a **Form FDA 1572.** Site Investigator at a non-USA Member Site of NACHO shall ensure completion of equivalent national requirements to the USA FDA 1572. Consortium Member shall ensure that Research Personnel involved in the conduct of the Study Protocol shall act in accordance with the terms of the Study Protocol, Rider and this Agreement. If Site Investigator cannot fulfill the duties under the Study Protocol, Rider and this Agreement, Consortium Member may nominate a replacement, which NACHO may approve or disapprove. In the event that the replacement is not approved, NACHO may terminate the Study Protocol, Rider and this Agreement in accordance with Article 2: Term and Termination.

3.3 Compliance with Applicable Laws, Regulations, and Standards.

(a) Consortium Member agrees that in carrying out its responsibilities under this Agreement, Consortium Member, Site Investigator, and Research Personnel will (i) conduct each Protocol in accordance with the Study Protocol, applicable Federal, state and local laws, regulations, and guidelines including 21 CFR 312 and 21 CFR 54; (ii) conditions of Institutional Review Board approval related to the Study Protocol in accordance with 21 CFR 56; (iii) written directions and instructions from the NACHO Principal Investigator; and (iv) good clinical practices as required under applicable portions of the Federal Food, Drug and Cosmetic Act, 21 USC 301 et seq. and its implementing regulations, and generally accepted standards of care.

(b) Consortium Member shall perform all duties under this Agreement in strict compliance with applicable international and U.S. Federal, state, and local laws, rules, and regulations, and shall comply with all applicable laws, rules, and regulations of all governmental authorities and accrediting agencies having jurisdiction over foundations, physicians, allied health professionals, and/or this Agreement, including export control laws, rules, and regulations with respect to use and distribution of tissue samples, and shall perform all duties under this Agreement in strict compliance with applicable international and U.S. Federal, state, and local laws, rules, and regulations, including the US Foreign Corrupt Practices Act, UK Bribery Act, the applicable standards of the World Medical Association, and the prevailing community standard of care. Consortium Member agrees to adhere to all the terms and conditions of grants, subawards and/or contracts from which funding is provided to Consortium Member by NACHO under this Agreement, and Consortium Member shall provide to NACHO or its designee necessary information, certifications, or documents required by the grants, subawards and/or

contracts as a condition of funding.

3.4 IRB Approval. Consortium Member shall obtain IRB review and approval of each Study Protocol and the Informed Consent Form ("ICF") in accordance with 21 CFR 56. Consortium Member shall provide St. Jude with written evidence of review and approval of the Study Protocol and Study ICF from its IRB prior to the initiation of the Study. The ICF must include a statement that data will be shared with St. Jude as the overall operations center, and the Data Safety Monitoring Board, if applicable.

3.5 Financial Disclosure. Consortium Member shall ensure the Site Investigator provides St. Jude with sufficient accurate financial disclosure information to permit St. Jude to submit a complete and accurate certification or disclosure statement as required by 21 C.F.R. part 54, and will promptly update the information if previously provided financial information is revised during the term of this Agreement, and for one (1) year following completion of the Study Protocol.

3.6 FWA and IRB. Consortium Member shall have a Federal Wide Assurance ("FWA") and a certified IRB, and shall provide proof of its FWA and IRB to St. Jude upon request.

4. Funding and Payments.

4.1 Payment and payment terms under this Agreement for each Study are made in accordance with the applicable Study Protocol budget as set forth in the Rider as **Attachment B**. Consortium Member acknowledges and agrees that payments hereunder are conditioned upon compliance with the terms and conditions of this Agreement, Rider, Study Protocol, and the receipt of funds from third parties. Payment beyond the term of individual budget periods from NACHO is contingent upon continued funding.

4.2 If the Parties conduct Sponsored Research, a separate Sponsored Research Agreement between St. Jude and the applicable Sponsor might be required.

4.3 Consortium Member shall submit monthly or quarterly invoices to the NACHO Operations Center for payments within the total authorized receipt of undisputed monthly or quarterly invoices for allowable costs incurred.

5. Ownership of Biological Samples.

5.1 Biological Samples shall be collected by Consortium Member and provided to the NACHO Operations Center or its designee, for the Study according to the Study Protocol and ICF as approved by the applicable IRB. Consortium Member and Site Investigator shall use biological Samples solely for purposes of the Protocol and only as specified in the Study Protocol, ICF, and this Agreement.

5.2 Biological Samples shall be owned by the Consortium Member that obtained or prepared them. In the event that the EC determines that it is desirable to bank Biological

Samples, Consortium Member shall cooperate with the NACHO Operations Center, which may request access to the Biological Samples in accordance with the applicable Study Protocol and NACHO SOPs.

5.3 The Consortium Member acknowledges and agrees that all Biological Samples shared between Consortium Members pursuant to this Section are provided on an **"as is"** basis and Consortium Member makes no representation or warranties (express or implied) that the Biological Samples are free from harmful biologicals, infectious agents, or organisms, or that they are otherwise fit for a particular use or purpose.

6. NACHO Data Policy, Record Keeping, Reporting.

6.1 Record Keeping. As required by applicable Protocol and/or Rider, Consortium Member shall maintain Records for submission to NACHO PI and the NACHO Operations Center. Consortium Member and Site Investigator agree to strictly adhere to NACHO SOPs regarding Access to Records, Record Retention, and Auditing Rights, as updated from time to time.

6.2 Data and Safety Monitoring Plan and Reports; Material Subject Information.

(a) When St. Jude has the responsibility to conduct data and safety monitoring on behalf of NACHO, NACHO shall include in the Protocol to be reviewed and approved by Consortium Members' IRB a plan for data and safety monitoring for the Study. Such plan will include, as appropriate to the Study Protocol, information about the provision of monitoring reports, including urgent and routine reports, or other pertinent determinations from the monitoring to the Site Investigator. In accordance with 21 C.F.R. § 312.50, 21 C.F.R. §312.55, and the FDA's Guidance on Adverse Event Reporting to Institutional Review Boards in Clinical Trials (January 2009), St. Jude and NACHO agree to promptly notify Site Investigator in writing of (1) information such as new and unexpected serious adverse safety events arising from St. Jude monitoring of the Study that could affect the safety of Subjects, and (2) trends or patterns of non-serious or expected adverse events that occur at a specificity or severity that is inconsistent with prior observations, including results obtained for a period of two years after Study conclusion or termination, that could affect the safety or medical care of subjects who were at any point enrolled in the Study, influence the conduct of the Study, or alter the IRB's approval. St. Jude, NACHO, and Consortium Member shall comply with, and nothing herein shall limit, their respective reporting requirements to regulatory authorities, including, for example, the Food and Drug Administration, the Office for Human Research Protections, and others as required. Consortium Member, through the Site Investigator and/or IRB as appropriate, shall be responsible for informing subjects of the above important information they learn from St. Jude and NACHO in accordance with the IRB-approved ICF. No other provision of this Agreement shall be construed to override the provisions of this Article 6.

(b) It is the responsibility of each NACHO member institution to follow their institution's approved Data Safety and Monitoring Plan (DSMP) for their site, such as an NCI-approved DSMP, and to be internally monitored by a Data Safety Monitoring Committee/Board (DSMC/DSMB). NACHO reserves the right to request a copy of such institutionally approved

DSMP, and note if it meets common regulatory standards. In addition to the guidelines laid out in this document, each NACHO member institution must comply with the policies and standards put forward by their own institutional DSMC/DSMB, if applicable. Institutions without an institutionally sanctioned DSMP will be electronically monitored and visited annually by the St. Jude monitoring oversight team.

6.3 Ownership and Use of Data.

(a) During the course of a NACHO Study, Consortium Member and/or Site Investigator shall collect and submit certain data to the NACHO Operations Center or its designee, as specified in the applicable Study Protocol. This includes Case Report Forms or equivalent, electronic data records, and other documents or materials created for the NACHO Study. Consortium Member and/or Site Investigator shall ensure accurate and timely collection, recording, and submission of data.

(b) Data shall be owned by the Consortium Member that generated it. A copy of all data collected under a Study Protocol shall be delivered in a mutually agreeably format to the NACHO Operations Center by Consortium Member in a timely manner throughout the performance of the NACHO Study Protocol. Consortium Member grants to the NACHO Operations Center the right to use its Data for scientific and educational purposes, and with the oversight of the EC, to meet reporting obligations.

(c) Consortium Members shall not have ownership rights in medical records or other primary source materials relating to Participants held by any other Consortium Member.

7. Confidential Information.

7.1 Consortium Member and Site Investigator acknowledge that, in the course of performing, carrying out, and fulfilling its duties and obligations in connection with the Study as required hereunder, Consortium Member and/or the Site Investigator, employees, contractors, or agents of the Consortium Member will have access to, will obtain, or will be provided with Confidential Information, directly or indirectly relating to St. Jude and/or its affiliates. Unmarked information that a reasonable person knowledgeable about clinical research would judge confidential will be treated as Confidential Information. The confidentiality provisions of this Agreement shall continue for a period of five (5) years after expiration or termination of this Agreement that is not Protected Health Information, as defined by The Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), or the Consortium Member country's national equivalent regulation.

7.2 Confidential Information shall not include information that:

(i) was in the possession of the Consortium Member or the Site Investigator prior to the date of disclosure by NACHO or St. Jude, as evidenced by written documentation existing prior to such disclosure; or

(ii) is lawfully received in good faith at any time by the Consortium Member or the Site Investigator from a third party without breach of an obligation of confidentiality owed to NACHO or St. Jude; or

(iii) is in the public domain or enters the public domain through no fault of the Consortium Member or the Site Investigator; or

(iv) was developed by the Consortium Member or the Site Investigator independent of any Confidential Information received from NACHO or St. Jude, as evidenced by written documentation.

7.3 Each Consortium Member is and will remain the sole and exclusive owner of its Confidential Information and any intellectual property rights in and to the Confidential Information, including patents, trade-marks, copyrights, industrial designs and trade secrets, and applications therefore. Consortium Members have no right or license of any kind regarding another Consortium Member's Confidential Information except as expressly provided herein.

7.4 Consortium Member agrees that it will use, and Consortium Member shall ensure that the Site Investigator shall use, Confidential Information only in connection with the performance of the Study, shall not disclose Confidential Information to persons other than those persons who need to know such Confidential Information for the sole purpose of performing the Study, and will safeguard Confidential Information by using the same degree of care, but no less than a reasonable degree of care, as the Consortium Member and Site Investigator use to protect their own confidential information.

7.5 Consortium Member acknowledges that breach of this, Article 7, may result in immediate and irreparable damage to St. Jude and its affiliates, therefore St. Jude shall be authorized and entitled to seek from any court of competent jurisdiction preliminary and permanent injunctive relief and an accounting of all profits and benefits arising out of such violation, which rights and remedies shall be cumulative and in addition to any other rights or remedies to which St. Jude may be entitled. Consortium Member shall be responsible for any and every violation of this Article 7 by its shareholders, directors, officers, employees, agents, advisors and/or affiliates.

7.6 Upon demand by NACHO or St. Jude, the Consortium Member and the Site Investigator shall promptly return or destroy, with written certification to St. Jude, the Confidential Information, including all copies thereof, to St. Jude.

7.7 In the event that the Consortium Member or the Site Investigator receives a request to produce Confidential Information pursuant to an order of a court of competent jurisdiction or a facially valid administrative, Congressional, state or local legislative or other subpoena, or believes that such party is otherwise required by law to disclose Confidential Information, then such party shall promptly notify St. Jude prior to making such disclosure, and shall provide St. Jude the opportunity to challenge or otherwise lawfully seek limits upon such disclosure of Confidential Information.

7.8 Equitable Remedy. The Parties acknowledge that a breach of this Section 7 may result in irreparable injury to the non-breaching Party for which money damages may not adequately compensate. In addition to the rights and remedies that the non-breaching Party may have under and pursuant to this Agreement or under applicable law, if a breach occurs, the non-breaching Party is entitled to seek an injunction issued by a competent court with jurisdiction to enjoin and restrain the breaching Party and other Parties involved from continuing the breach. The existence of another claim or cause of action that the breaching or another Party may have against the non-breaching Party shall not constitute a defense or bar to the enforcement of this provision.

8. Protection of Personal Information.

8.1 Personal Information. The Parties to this Agreement recognize that performance under the Agreement may involve the exchange of certain information about individuals ("Personal Information"). Personal Information may include individually identifiable health, employment, insurance, and family information. Personal Information shall be collected, transmitted, handled, stored, maintained, used, and eliminated in a manner that preserves confidentiality of the Personal Information. All Parties to this Agreement shall maintain confidentiality of patient records at all times as required by applicable law. Unless mutually agreed in writing by all Parties, and in compliance with applicable laws and regulations, the Parties will not use or disclose Personal Information that they receive pursuant to this Agreement for any purpose other than the performance of this Agreement. Without limiting the foregoing, the Parties agree to comply with requirements of law relating to PHI including, but not limited to, the Federal Health Insurance Portability and Accountability Act of 1996 set forth at 42 U.S.C. § 1320d et seq, or the Consortium Member country's national equivalent regulation. Each Party to whom HIPAA applies shall comply with HIPAA standards applicable to it in all respects, including implementation of necessary safeguards to prevent disclosure, and shall assure that subcontractors and agents to whom the Party has provided Confidential Patient Information agree to the same restrictions and conditions imposed on the Parties hereto under HIPAA.

9. Use of Name.

9.1 The Consortium Member, the Site Investigator, and their respective employees, agents and representatives shall not communicate with or provide any information to any media, including, but not limited to, traditional and alternative press outlets such as newspapers, magazines, television, radio and Internet, representative regarding St. Jude, NACHO, the Studies, or names of any current or former St. Jude employees or affiliated physicians or faculty without the prior express written approval of St. Jude. In addition, St. Jude, the Consortium Member, and the Site Investigator shall not use, expressly or by implication, any product image or likeness, name, logo, trademark or trade name of any other Consortium Member, or any contraction, abbreviation, simulation or adaptation thereof, in any news or publicity release, policy, recommendation, advertising or any other commercial communication without the prior written approval of the other Consortium Member, which, in the case of St. Jude, is valid only if given by its Senior Vice President for Communications; provided, however, that the limitations contained in this Article 9 shall not apply to any documents that may be necessary or appropriate for NACHO, St. Jude, or the Consortium Member to provide to a federal, state, or local

governmental agency or in scientific publications and grant applications. A Party may disclose its factual affiliation, relationship, and participation with NACHO for informational purposes such as in Consortium Member publications and web sites. Notwithstanding the foregoing, St. Jude, in its sole discretion, may use, publish or otherwise publicly disclose the existence and nature of St. Jude's contractual relationship with the Consortium Member and/or the Site Investigator.

10. Publication.

10.1 NACHO Study Protocols are multi-center trials and as such, Consortium Members shall have the right to publish the results of the trials solely in accordance with the NACHO SOPs. The NACHO Operations Center will notify the Site Investigator of changes to the SOP. Should a multi-center publication not materialize within twenty-four (24) months after the multi-center study is completed at all Participating Sites, the Site Investigator may publish/present Consortium Member's individual Study Data without restriction.

10.2 The Consortium Member shall acknowledge the appropriate Study Sponsor as provided in the application Rider or as requested by the NACHO Operation Center.

10.3 Registration of Study. Prior to enrollment of the first subject in the Study, NACHO shall register the Study with www.clinicaltrials.gov, and equivalent registries, including all information recommended by the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors (see www.icmje.org).

11. Inventions.

11.1. Inventorship of any invention or discovery, whether patentable or non-patentable, that is conceived or reduced to practice in the course of and during the performance of a NACHO Study ("Invention"), will be determined in accordance with principles of United States Patent Law. In the case of a non-patentable invention, inventorship will be determined by treating the invention as if it were patentable. If an Invention is made by one or more inventors, all of whom are required to assign rights in the Invention to a single Consortium Member, then the Invention shall be the property of that Consortium Member. If one or more inventors make an Invention, where the inventors are required to assign rights in the invention to more than one Consortium Member, the Invention shall be jointly owned by the Consortium Members who are assigned rights in the Invention ("Joint Invention").

11.2 Notwithstanding any purported exclusive license to Inventions granted by a Consortium Member to a third party, each Consortium Member shall have an unrestricted right to practice any invention for its own non-commercial clinical, education and research purposes. Any exclusive license granting rights to Inventions shall be made explicitly subject to this right.

11.3 Unless specified otherwise in a Rider, each Consortium Member separately reserves the right to license its interest in any Invention, subject to the other party's right to use the Invention for its own non-commercial clinical, education and research purposes. For Joint Inventions, the inventing parties may decide to enter in an Inter-Institutional Agreement

addressing, among other things, patenting, marketing, licensing and revenue sharing related to such Joint Invention. In the event the parties decide not to enter into an Inter-institutional Agreement, each party shall be free to independently license its interest in any Joint Invention.

12. Study Subject Injury.

12.1. For a Study Protocol utilizing a drug or material provided by a third party, St. Jude agrees to negotiate in good faith: (a) indemnification of St. Jude and the Participating Site by the third party drug and/or material provider for claims arising from the use of such third party provided drug or material in the Study Protocol; and (b) coverage by the third party drug and/or material provider for injury to Protocol Participants arising from introduction of the third party provided drug to such Protocol Participants in performance of the Study Protocol. Notwithstanding the foregoing, St. Jude does not guarantee that it will be able to secure such indemnification or subject injury coverage from any third party and St. Jude and Participating Site acknowledge that each Party will participate in any Study Protocol in the absence of such indemnification and/or subject injury coverage in its sole discretion. It is not St. Jude's policy to provide payment if subject's are injured from being in the Protocol.

13. Indemnity and Insurance.

13.1 No Consortium Member shall indemnify, or seek indemnification from, St. Jude or the NACHO Operations Center or another Consortium Member for actions or results related to this Agreement or a NACHO Study. Each Consortium Member shall maintain commercially reasonable insurance, and evidence of such insurance shall be supplied to NACHO upon request.

13.2 Consequential Damages. Except as to breach of confidentiality obligations, no Party is responsible to another Party for lost profits or consequential, punitive, or indirect damages arising out of, relating to, or under this Agreement.

14. Notices.

Communications, reports, and notices required or permitted hereunder shall be deemed sufficiently given if in writing and personally delivered or sent by registered mail, postage prepaid, return receipt requested, addressed to the Parties as follows or at such other address as a Party shall have given notice of pursuant hereto:

To St. Jude/NACHO:

Matters of an administrative nature: St. Jude Children's Research Hospital, Inc.
262 Danny Thomas Place, MS 721
Memphis, Tennessee 38105
Attn: Beth Anne Miller, MNM
Phone: (901) 595-6873
bethanne.miller@stjude.org (effective 3/7/2016)
betha_miller@dfci.harvard.edu (until 3/4/2016)

Matters of a scientific nature:

St. Jude Children's Research Hospital, Inc.
262 Danny Thomas Place, MS 721
Memphis, Tennessee 38105
Attn: Carlos Rodriguez-Galindo, M.D.
Phone: (901) 595-7573
carlos.rodriguez-galindo@stjude.org

If to Consortium Member:

Any notices required or permitted under this Agreement shall be in writing and addressed to addresses or facsimile numbers of the Parties as shown on the signature page.

15. Laws and Regulations.

15.1 Parties shall cooperate in complying with applicable Federal, state, and local laws, regulations, and policies governing research. The Parties represent and warrant that they shall:

(a) Perform the Study in accordance with applicable US laws and regulations, or the Consortium Member country's national equivalent regulations, including but not limited to the regulations set forth in FDA Form FD 1572, 21 CFR, part 50 (Federal Register, January 1981; 46(17): 8942), and Part 56 (Federal Register, January 1981; 46(17): 8975), Good Clinical Practice Guidelines, and good clinical practice requirements that the FDA may publish from time to time, perform laboratory analyses in accordance with applicable academic research standards, and comply with new requirements if regulatory requirements change; and

(b) Exercise independent medical judgment of Consortium Member compliance with the Study requirements; notify the other Parties within the timelines set forth in 21 CFR Parts 50 and 56 of significant or material deviations from the Study; report adverse events and experiences in accordance with 21 C.F.R. Part 312 and the Study Protocol; record Study Protocol deviations in the Study records; and use best efforts to remedy Study Protocol violations and deviations; and

(c) Not pay fees for patient referral to the Study.

16. Rider; No Assignment.

16.1 Rider. Consortium Member shall execute a Rider, attached hereto as **Exhibit A**, prior to commencing work under the Study Protocol.

16.2 Non-Assignment. Consortium Member may not assign or transfer in whole or in part any rights or obligations under this Agreement without the prior written consent of St. Jude.

17. Force Majeure.

17.1 A Party will not be liable for failure or delay in performing its obligations under this Agreement if the failure or delay is not a result of its own conduct but required to comply with a government law, regulation, or order, or is caused by other circumstances beyond the reasonable control of the Party. A Party claiming force majeure will promptly notify the other Parties in writing, with an explanation. It will use reasonable efforts to resume performance of its obligations under this Agreement. If the failure or delay extends for more than three (3) months, then the Parties shall have the right to terminate this Agreement upon written notice at any time after expiration of the three (3) month period. This provision is subject to the termination obligations set forth in Article 2 of this Agreement**.**

18. Export Control.

18.1 The Parties are subject to United States laws and regulations controlling the transfer of goods, software, and technology, including technical data, laboratory prototypes, biologics, and other commodities. The Parties shall comply with applicable laws and regulations including the Export Control Act, the International Traffic in Arms Regulations, the Export Administration Regulations, and the laws and regulations implemented by the Office of Foreign Assets Control, U.S. Department of the Treasury. Diversion contrary to U.S. law is prohibited. Each Party further agrees that no materials or data subject to export control laws or regulations shall be transferred to the other Party without first obtaining the written permission of both Parties' Office of Research Responsibility or equivalent authorized institutional official.

19. Anti-Terrorism.

19.1 The Parties acknowledge that they are familiar with the U.S. Executive Orders and laws that prohibit the provision of resources and support to individuals and organizations associated with terrorism and the terrorist-related lists promulgated by the U.S. Government, the United Nations, and the European Union. Consortium Member shall use reasonable efforts to ensure that none of the funds that NACHO provides under this Agreement will be used in support of or to promote violence, terrorist activity, or related training or money laundering. Consortium Member warrants that to the best of its current knowledge, it has not provided, and shall take reasonable steps to ensure that it does not and will not knowingly during the term of this Agreement, provide support or resources to any individual or entity that does or has committed, attempted to commit, advocated, facilitated, or participated in violence, terrorist acts, or money laundering.

20. Miscellaneous.

20.1 Severability. If a court or tribunal of competent jurisdiction finds a provision of this Agreement legally invalid or unenforceable, either the provision shall be severed from this Agreement and shall not affect the validity of the remainder of this Agreement, or the Parties will negotiate and revise the provision to make it valid and enforceable.

20.2 Remedies and Waivers. If a Party breaches or defaults on a term in this Agreement, the Parties may pursue all legal and equitable contractual and other remedies. All rights, powers, and remedies granted to a Party by a term in this Agreement are in addition to, and not in limitation of, rights, powers, and remedies that the Party has under another term of this Agreement, at common law, in equity, by statute, or otherwise, and which may be exercised separately or concurrently, in the order and as often as the Party deems expedient. A waiver of a provision in this Agreement shall be in writing and signed by the Parties; failure to enforce a provision shall not constitute a general waiver of that provision or prevent the waiving Party from acting upon that or a subsequent breach, or from enforcing a term or condition of this Agreement.

20.3 Relationship of the Parties. For the purposes of this Agreement and all Studies and Services to be performed hereunder, Research Personnel are, and shall be deemed to be, independent contractors, and not agents or employees of St. Jude or NACHO. Site Investigator and Consortium Member shall not have any authority, and shall not give the appearance of having any authority, to make statements, representations, or commitments of any kind, or to take any action which would be binding on St. Jude or NACHO, except as may be expressly provided for or authorized in writing.

20.4 Modification and Amendment. This Agreement, including those documents attached hereto or referenced herein, supersede prior oral or written communications among the Parties and constitutes the entire agreement and understanding of the NACHO Operations Center, St. Jude, Consortium Member, Principal Investigator and NACHO Site Investigator, and any amendments mutually agreed upon in writing are the complete and entire agreement regarding the Studies and Services to be performed hereunder. Consortium Member and St. Jude may amend this Agreement in writing to make changes within the general scope of the Study, and may revise, delete, or add terms to the Study or Study Protocol, revise the period or schedule of performance, and amend the budget. Modifications shall be effective only upon execution of a signed, dated, written amendment to this Agreement.

20.5 Rights and duties under Articles 2 [Term and Termination], 5 [Biological Samples and Study Drug], 6 [Reporting, Record Keeping, Regulatory Inspections and Audits], 7 [Confidential Information, 9 [Use of the Names of the Parties], 10 [Publication], 11 [Inventions and Patents], 13 [Indemnification], 14 [Notice], 15 [Laws and Regulations], 18 [Export Control], and 20 [Miscellaneous] of this Agreement shall survive termination or expiration of this Agreement.

20.6 Representation and Comprehension. The Parties have read this Agreement, fully understand and voluntarily accept its terms of their own free choice and with full knowledge of its significance, have had sufficient time and opportunity to review this Agreement and consult with legal counsel or other advisers of their choosing, and have executed this Agreement of their own free will.

20.7 Successors. This Agreement shall be binding upon and inure to the benefit of the Parties, their heirs, legal representatives, successors, and assigns.

20.8 Third Party Beneficiaries. This Agreement does not create and shall not be construed to create legal rights enforceable by a person not a Party to this Agreement.

20.9 Governing Law And Jurisdiction. Except as otherwise provided in this agreement, a dispute not disposed of fully and by mutual consent shall be decided by judicial choice of law rules and procedures jointly agreed upon by the parties.

20.10 Attorneys Fees. If a Party institutes an action or proceeding in court to enforce a provision in this Agreement, or for damages caused by an alleged breach of a provision in this Agreement, the prevailing Party(s) are entitled to recover from the losing Party(s) the amount the court adjudges reasonable attorneys' fees. The provisions of this Article 20.10 shall be continuing and shall survive termination or expiration of this Agreement.

20.11 Limitation of Obligation. The obligations of the Parties are limited to those set out in this Agreement. St. Jude will coordinate the Consortium Members' activities; however, the Consortium Member and Site Investigator are responsible for their own activities under this Agreement.

20.12 Non-Solicitation. For twelve (12) months after execution of this Agreement, the Parties and their contractors associated with the Study Protocol shall not take intentional action to solicit or cause to be solicited for employment or contracting an employee or contractor of another Party associated with the Study.

20.13 Non-Exclusivity. Nothing in this Agreement limits the right of the Parties to affiliate or contract with a third party on either a limited or general basis while this Agreement is in effect.

20.14 Headings. The headings of the Articles and Attachments of this Agreement are inserted for convenience of reference only and shall not in any manner affect the construction or meaning of anything contained in this Agreement, or govern the rights or liabilities of the Parties.

20.15 Prohibition Against Discrimination. The Parties shall not discriminate against an individual or group on the basis of race, religion, age, sex, disability, veteran's status, or national origin. Notwithstanding the foregoing, the Parties will respect scientifically valid Study Subject exclusion and inclusion criteria established for this Study Protocol.

20.16 Counterparts. This Agreement may be executed in two or more counterpart copies, each of which constitutes an original, and all together constitute the complete Agreement. Photocopy, facsimile, electronic scan, or other copies shall have the same effect for all purposes as an ink-signed original. Execution is complete when each party holds a copy of this Agreement, whether transmitted by facsimile or in publication or portable document format form, signed by the other Parties, even though the signatures of all Parties do not appear on the same copy. Each Party consents to be bound by electronic, photocopy, or facsimile signatures of the Party's representative.

24.7 Debarment. Consortium Member ensures that Consortium Member, Site Investigator and Research Personnel have never been, are not currently, and during the term of this Agreement, will not be debarred or otherwise disqualified under the provisions of 21 U.S.C. 335 (a) and (b). In addition, Consortium Member represents and ensures that Consortium Member, Site Investigator and Research Personnel have not engaged in any conduct or activity that could lead to any of the above-mentioned debarment or disqualification actions.

24.8 Warranty Disclaimer. Consortium Member and Site Investigator each understands and agrees that no warranty, either express or implied, is made by NACHO with respect to the efficacy of the Study.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]

IN WITNESS WHEREOF, the Parties agree to the above terms, have caused this Agreement to be executed and delivered by their authorized representatives, and acknowledge receipt of a copy of this Agreement.

ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC./ NACHO

By: _____
Name: James Downing, MD or designee
Title: President and CEO
Date: 2-23-16

NACHO PARTICIPATING SITE/CONSORTIUM MEMBER

By: _____
Print Name: _____
Title: _____
Date: _____
Institution Name: _____
Address: _____
Phone: _____ Facsimile: _____

EXHIBIT A

CLINICAL STUDY PROTOCOL RIDER

This Clinical Study Protocol Rider ("Rider"), is entered into as of the __th day of _____, **20_** (the "Effective Date") by and between **St. Jude Children's Research Hospital Inc.** ("St. Jude"), and **the NACHO Participating Site** signatory ("Consortium Member").

Individually each is a "Party" and together are the "Parties."

WITNESSETH:

WHEREAS, institutions that are members of the North American Consortium for Histiocytosis ("NACHO") engage in research activities and services, including creation, implementation, and documentation of clinical research, testing, and trials through research study protocols approved by one or more Institutional Review Boards; and

WHEREAS, institutions may choose to participate in a Study Protocol ("Consortium Member"); and

WHEREAS, the Study Protocol attached by reference to the Rider as **Attachment A** will further the NACHO research objectives consistent with its mission; and

WHEREAS, the Consortium Member desires to participate in the Study Protocol under the terms and conditions of the Agreement; and

WHEREAS, NACHO shall permit the Consortium Member and the Site Investigator to participate in the Study Protocol, in exchange for the Consortium Member's execution of this Rider, and compliance with its terms and the terms of the Agreement.

WHEREAS, Consortium Member and Site Investigator will execute this Agreement for Study Protocol entitled "_____" ; and

WHEREAS, Consortium Member has facilities, personnel, and support sufficient to perform and adhere to the Study Protocol, the terms of this Rider and the Agreement, and Good Clinical Practice Guidelines as set forth in Title 21 of the U.S. Code of Federal Regulations, or the Consortium Member country's national equivalent regulation; and

WHEREAS, St. Jude has facilities, personnel, and support to coordinate the Study Protocol with the Consortium Member.

NOW, THEREFORE, in consideration of the promises and covenants contained herein, the Parties agree as follows:

(1) Capitalized terms in this Rider shall have the same meaning as defined and used in the Agreement.

(2) This Rider is attached to and its terms are incorporated into the Agreement and the Study Protocol terms are binding upon St. Jude and Consortium Member in conduct of the Study Protocol.

(3) The Consortium Member shall participate in the Study Protocol with the attendant rights and obligations identified in the Agreement, Study Protocol, and this Rider.

(4) The Consortium Member has the expertise, time, and resources to conduct the Study Protocol, will conduct the Study Protocol in a timely manner and in accordance with this Rider, the Study Protocol, and NACHO's written instructions, and will collect and record Study Data accurately.

(5) The Study Protocol is effective upon the Consortium Member's IRB approval; however, NACHO may modify the Study Protocol with IRB approval, effective upon notice to Consortium Member. Consortium Member may not modify the Study Protocol, but may propose changes to NACHO and request exceptions to the Study Protocol, which NACHO and, when appropriate, the IRB must approve in writing.

(6) NACHO shall promptly report to Site Investigator information that could directly affect the health or safety of Study Subjects or influence the Study Protocol, Study Results, and information in site monitoring reports and data safety monitoring committee reports. The Site Investigator and Consortium Member may communicate the findings to Study Subjects and the Consortium Member IRB.

(7) Consortium Member shall conduct the Study in conformance with generally accepted standards of good clinical practice and in accordance with applicable Federal, state, and local laws and regulations, or the Consortium Member country's national equivalent regulation.

(8) Consortium Member represents that:

(a) By signing this Rider that (i) neither the Consortium Member nor any individuals who will perform any of the work described in the Agreement on behalf of Consortium Member are presently debarred, suspended, or declared ineligible by any Federal Agency or have voluntarily excluded themselves from participation in covered transactions, pursuant to Title 45, CFR, part 76, and (ii) no such individuals shall perform any work described in the Agreement; and

(b) It has a system for discovering these actions in the United States; and

(c) It will notify NACHO and St. Jude promptly of an actual disqualification, debarment, suspension, or other ban of the Consortium Member or any individuals who will perform any of the work described in the Rider on behalf of Consortium Member that comes to its attention during the course of the Study and for five (5) years thereafter;

and it and Site Investigator have no conflict of interest that would affect conduct of the Study Protocol; and

(d) It and Site Investigator have no conflict of interest that would affect conduct of the Study Protocol; and

(e) It and Site Investigator will notify NACHO and St. Jude promptly if a conflict of interest arises during the term of this Agreement; and

(f) It and Site Investigator will not enter into a financial security transaction based on Study Data or Study Results.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]

IN WITNESS WHEREOF, the Parties have caused this Rider to be executed and delivered by their authorized representatives.

ST. JUDE CHILDREN'S RESEARCH HOSPITAL, INC.

By:_____
Name: James Downing, M.D. or designee
Title: President and CEO
Date: _____

NACHO PARTICIPATING SITE/CONSORTIUM MEMBER

By:_____
Name: _____
Title:_____
Date: _____
Institution Name: _____
Address: _____
Phone: _____Facsimile: _____

Read and Understood by SITE INVESTIGATOR
By:_____
Name: _____
Title:_____
Date: _____

ATTACHMENT A
Study Protocol

ATTACHMENT B
Budget