

Enclosed please find ALCMI's *Master Collaboration Agreement* (MCA). This rather comprehensive MCA brings member institutions into ALCMI as a consortium, and specific research projects are incorporated via a simple one page Research Study Agreement (study name, PI, institutional and ALCMI signatures). To date, the MCA has been executed by the following institutions and organizations:

1. Alta Bates Summit Medical Center (Oakland, CA)
2. Dana-Farber Cancer Institute (Boston, MA)
3. Hoag Hospital (Newport Beach, CA)
4. Institute Gustave Roussy (Paris, France)
5. Lahey Clinic Hospital (Burlington, MA)
6. Memorial Health System (Hollywood, FL)
7. New York University Medical Center (New York, NY)
8. Northside Hospital (Atlanta, GA--recently approved, not yet executed)
9. Palo Alto Medical Foundation (Bay Area (regional), CA)
10. U. of California, San Francisco (San Francisco, CA)
11. U. of California at Davis (Sacramento, CA)
12. U. of Southern California (Los Angeles, CA)
13. Vanderbilt University (Nashville, TN)
14. WellStar Healthcare System (Atlanta, GA--recently approved, not yet executed)
15. Yale University (New Haven, CT--recently approved, not yet executed)

The MCA is presented to potential collaborators as "take it or leave it"--**no** changes will be made other than to the indemnification section to comply with varying state/national laws. Thus every collaborating member has the same rights/obligations within the consortium. ALCMI serves as the lead negotiator on any additional agreements with external research partners (industry, government, etc.) In my view the MCA is an invaluable document for any disease-focused groups that are considering establishing a translational/basic research consortium. ALCMI hereby contributes our MCA to FasterCures TRAIN for the unrestricted use/adaptation by any non-profit organization. Although certainly not a requirement, I'd be very interested in hearing from any such group(s) if they make use of the MCA.

The second master agreement establishing ALCMI as a consortium addresses IP/inventions. I plan to finalize (it's greater than 90% done) this over the next months and I'll provide to TRAIN at that time. The latter document is termed our *Innovation and Commercialization Agreement*.

Regards,  
Steven

Steven W. Young  
President  
Addario Lung Cancer Medical Institute (ALCMI; "Alchemy")

Office: (203) 226-5765  
Cell: (203) 247-9035

**DATE**

**MASTER COLLABORATION AGREEMENT**

**ADDARIO LUNG CANCER MEDICAL INSTITUTE**

**and**

**INSTITUTION**

**DATE**

## TABLE OF CONTENTS

	<b>Page</b>
ARTICLE 1 DEFINITIONS.....	1
1.1 Defined Terms .....	1
ARTICLE 2 PURPOSE AND SCOPE.....	1
2.1 Purpose.....	1
2.2 Scope.....	2
2.3 Non-Exclusivity Provision.....	2
2.4 Relationship of the Institutions .....	2
2.5 Scope of Institution’s Obligations .....	3
2.6 Third Party Beneficiaries .....	3
ARTICLE 3 THE COLLABORATIVE EFFORT .....	3
3.1 Overview of the Collaborative Effort Components .....	3
3.2 Scientific Leadership Board (“SLB”) .....	3
3.3 ALCMI Research Projects .....	4
ARTICLE 4 ALCMI SERVICES AND OBLIGATIONS .....	5
4.1 ALCMI Policies .....	5
4.2 Collaborative Effort Membership .....	5
4.3 Soliciting Funding.....	5
4.4 ALCMI Research Project Funding .....	5
4.5 Lead Negotiator .....	5
4.6 Personnel.....	6
4.7 ALCMI Repositories.....	6
4.8 Results.....	6
4.9 Exclusions.....	6
ARTICLE 5 COLLABORATING INSTITUTION PARTICIPATION .....	7
5.1 Investigator Acknowledgement .....	7
5.2 Institution Representations.....	7
5.3 Research Study Agreements .....	8
5.4 Assets .....	10
5.5 Support for ALCMI Research Projects.....	10
5.6 Collaborating Personnel.....	11
5.7 Obligations of the Institution When Serving as a Participating Institution for ALCMI Research Projects .....	11
5.8 Special Requirements of the Institution When Serving as a Participating Institution for Bench Research.....	14

DATE

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
5.9 Special Requirements of the Institution When Serving as a Participating Institution for Clinical Research .....	14
5.10 Special Requirements for Animal Research .....	15
5.11 Subcontractor; Affiliates .....	16
5.12 Institution Noncompliance .....	16
ARTICLE 6 TERM AND TERMINATION .....	17
6.1 Term .....	17
6.2 Termination of this Agreement for Cause .....	17
6.3 Termination of this Agreement Upon the Advice of Counsel .....	17
6.4 Termination without Cause .....	17
6.5 Termination of a Research Study Agreement .....	17
6.6 Effect of Termination of the Agreement .....	18
6.7 Remedies in Addition .....	19
ARTICLE 7 INSURANCE .....	19
7.1 Institution Insurance .....	19
7.2 ALCMI Insurance .....	19
ARTICLE 8 CONFIDENTIALITY .....	19
8.1 Generally .....	19
8.2 Confidential Information .....	19
8.3 Third Party Confidential Information .....	20
8.4 Exclusions .....	20
8.5 Relief .....	21
ARTICLE 9 INDEMNIFICATION .....	21
9.1 Generally .....	21
9.2 Indemnification of the Institution by ALCMI .....	21
9.3 Indemnification of ALCMI by the Institution .....	21
9.4 Subcontractors .....	22
9.5 Notification .....	22
9.6 Duty to Cooperate .....	22
9.7 Notice; Settlement .....	22
9.8 Limitation on Liability .....	22
9.9 DISCLAIMER OF WARRANTIES .....	22
ARTICLE 10 DISPUTE RESOLUTION .....	23
10.1 Disputes .....	23
10.2 Resolution By Mutual Agreement .....	23

DATE

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
10.3 Mediation .....	23
10.4 Interim Relief .....	23
ARTICLE 11 PUBLICATION .....	24
11.1 Publication .....	24
11.2 Non-Disclosure .....	24
11.3 Timeliness of Publications .....	25
11.4 Types of Publications .....	25
11.5 Notice of Publication; Reprints .....	25
ARTICLE 12 USE OF NAME .....	25
12.1 Generally .....	26
12.2 Announcements .....	26
12.3 Advertising .....	26
ARTICLE 13 MISCELLANEOUS .....	27
13.1 Amendments .....	27
13.2 Assignment .....	27
13.3 Construction .....	27
13.4 Execution .....	27
13.5 Force Majeure .....	27
13.6 Headings; Exhibits .....	27
13.7 Notices .....	27
13.8 Change in Laws; Severability .....	28
13.9 Survival .....	28
13.10 Waiver .....	28

March 8, 2011

## **MASTER COLLABORATION AGREEMENT**

THIS MASTER COLLABORATION AGREEMENT (the “**Agreement**”), effective as of March 8, 2011 (the “**Effective Date**”), is entered into by and between the Addario Lung Cancer Medical Institute (hereinafter “**ALCMI**”), a non-profit corporation, with a principal place of business at 1100 Industrial Road, Suite 1, San Carlos, CA 94070 and **INSTITUTION**, a not-for-profit Massachusetts corporation, with a principal place of business at **ADDRESS** (the “**Institution**” and together with ALCMI, collectively referred to as the “**Parties**” and each a “**Party**”).

### **BACKGROUND**

**WHEREAS**, the Institution is academic medical center recognized as exempt from federal income tax as an organization described in Section 501(c)(3) of the Internal Revenue Code and as other than a private foundation under Section 509(a)(1) or 509(a)(2) of the Internal Revenue Code, and has scientific and clinical expertise in treating lung cancer;

**WHEREAS**, ALCMI is recognized as exempt from federal income tax as an organization described in Section 501(c)(3) of the Internal Revenue Code, and is dedicated to facilitating and accelerating medical discoveries in the field of lung cancer diagnosis and treatment by establishing a network of (i) universities, institutions, hospitals, hospital systems, and other institutional providers, including the undersigned Institution, that wish to work with ALCMI and support ALCMI’s mission by conducting coordinated, translational ALCMI Research Projects (each, a “**Collaborating Institution**”) and has signed a Master Collaboration Agreement; and (ii) qualified physicians, scientists, and other personnel employed by or affiliated with Collaborating Institutions who work on an ALCMI Research Project (“**Collaborating Personnel**”) (together, the “**Collaborative Effort**”); and

**WHEREAS**, the Institution wishes to participate as a Collaborating Institution and employs individuals eligible to serve as Collaborating Personnel according to the terms of this Agreement.

**NOW THEREFORE**, for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

### **ARTICLE 1** **Definitions**

- 1.1 **Defined Terms**. Capitalized words and expressions in this Agreement will have the meanings set forth in **Exhibit A** or elsewhere herein. Non-capitalized terms and expressions will have their common and ordinary meaning.

### **ARTICLE 2** **Purpose and Scope**

- 2.1 **Purpose**. ALCMI’s mission is to foster collaboration and to further advance scientific knowledge and discoveries in the field of lung cancer with a focus on developing an

improved understanding of lung cancer as a disease from a basic and/or translational standpoint in order to facilitate the development of more effective and targeted novel therapies, including accelerated commercialization of medical innovation for the public good. ALCMI believes that too often leading scientists operate in isolation pursuing duplicative and uncoordinated Research. ALCMI promotes a different approach in which Collaborating Personnel from different Collaborating Institutions ally to conduct coordinated Research Studies in the Field using one or more of the resources provided by ALCMI and further described in Article 3 (each an “**ALCMI Research Project**”). ALCMI provides infrastructure, business/research operations, direction, and financial support to foster ALCMI Research Projects and to protect and commercialize resulting innovation. To set expectations consistently among participants, and to ensure that value and contribution is recognized multilaterally, ALCMI wishes to enter into a Master Collaboration Agreement with each Collaborating Institution, substantially similar to this Agreement, and a Memorandum of Understanding for the execution of an Innovation and Commercialization Agreement (“**MOU**”). The Innovation and Commercialization Agreements shall be substantially similar for all Collaborating Institutions.

- 2.2 Scope. This Agreement shall govern the Parties’ roles and responsibilities with respect to the Collaborative Effort described in this Agreement and for every ALCMI Research Project in which the Institution participates, and shall govern the Institution’s obligations to assist ALCMI, as described in Article 5. This Agreement, including the MOU and the subsequent separately executable Innovation and Commercialization Agreement and any other future written agreement signed by the authorized signatories of the Parties to effect the terms of this Agreement or the Innovation and Commercialization Agreement, shall constitute the entire agreement between the Parties with respect to the subject matter hereof, and all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, are null and void and of no effect. In addition to the foregoing, at the discretion of ALCMI, certain Collaborating Institutions may furnish other services, equipment or materials as mutually agreed by ALCMI and the applicable Collaborating Institution(s) from time to time in writing.
- 2.3 Non-Exclusivity Provision. This Agreement does not create an exclusive relationship between the Parties, and any activities in furtherance of the Collaborative Effort requiring exclusivity will be specifically defined and agreed upon by the Parties as an amendment to this Agreement or in a separate agreement.
- 2.4 Relationship of the Institutions. The Parties acknowledge that this Agreement does not create a fiduciary relationship between them, that each Party is an independent contractor of the other Party, and that nothing in this Agreement is intended to make either Party an agent, legal representative, subsidiary, joint venturer, partner, employee or servant of the other for any purpose whatsoever. A Party will not have the power to exercise dominion or control over the other Party’s operations, except as expressly provided herein. The Parties further acknowledge that this Agreement does not create a fiduciary relationship between any Collaborating Personnel and ALCMI. Nothing in this Agreement is intended to make any Collaborating Personnel an agent, legal representative, subsidiary, joint venturer, partner, employee, or servant of ALCMI for any purpose.

March 8, 2011

- 2.5 Scope of Institution's Obligations. The Institution agrees that in addition to the obligations enumerated herein specifically assigned to "Institution," whenever it is acting as a Collaborating Institution, it will abide by all provisions set forth in this Agreement applicable to Collaborating Institutions and that whenever it is acting as a Participating Institution, it will abide by all provisions set forth in this Agreement applicable to Participating Institutions.
- 2.6 Third Party Beneficiaries. ALCMI and each Collaborating Institution shall enter into a Master Collaboration Agreement substantially similar to this Agreement. Each Collaborating Institution shall be a third party beneficiary of any Master Collaboration Agreement entered into by ALCMI and any other Collaborating Institution.

### **ARTICLE 3** **The Collaborative Effort**

- 3.1 Overview of the Collaborative Effort Components. In furtherance of the purposes set forth in Section 2.1, ALCMI has created the Collaborative Effort, which principally consists of the four following components, summarized in this Section 3.1 and further described in the Agreement.
- 3.1.1 As further described in Section 3.2, ALCMI has established, or will establish, a Scientific Leadership Board (the "**Scientific Leadership Board**" or "**SLB**") to assist ALCMI in pursuing its mission and to guide the Collaborative Effort.
  - 3.1.2 As further described in Section 4.7, ALCMI has established, or will establish, as promptly as is reasonably possible, one or more repositories of Tissue (each, an "**ALCMI Tissue Bank**"), and one or more data banks (each an "**ALCMI Databank**" and together with the ALCMI Tissue Banks, the "**ALCMI Repositories**").
  - 3.1.3 As further described in Section 4.3, ALCMI will provide ALCMI Funding and assist seeking Third Party Funding.
  - 3.1.4 ALCMI will work with the Collaborating Institutions to develop an integrated, strategic and equitable approach to Intellectual Property, designed to balance the goals of openness, due credit, and fast-track commercialization, pursuant to the MOU, to be set forth in the Innovation and Commercialization Agreement.
- 3.2 Scientific Leadership Board ("SLB").
- 3.2.1 The SLB shall consist of one (1) representative from ALCMI, and one (1) representative selected by ALCMI from Collaborating Institutions selected by ALCMI; provided that a Collaborating Institution may decline the appointment of its own Collaborating Personnel to the SLB or may nominate its own Collaborating Personnel to be considered for membership on the SLB by ALCMI.

March 8, 2011

- 3.2.2 The SLB shall issue policies and protocols for membership, governance, and any other function of the SLB, which may include a regular meeting schedule and/or minimum participation requirements at SLB meetings.
- 3.2.3 The SLB shall, inter alia, review ALCMI Research Project Proposals and recommend whether or not to approve an ALCMI Research Project Proposal in writing. Each SLB member shall be entitled to one (1) vote in approving a Research Project Proposal. Notwithstanding the foregoing, ALCMI has no obligation to adopt or otherwise accept any action proposed by the SLB, including accepting any ALCMI Research Property Proposal supported by the SLB as an ALCMI Research Project.
- 3.2.4 An ALCMI Research Project Proposal may be developed or submitted to the SLB by any Collaborating Personnel in a variety of manners or processes; provided, however, that the ALCMI Research Project Proposal meets the requirements set forth in Section 3.3.1 herein.

### 3.3 ALCMI Research Projects.

- 3.3.1 An ALCMI Research Project Proposal will include, but need not be limited to, the following information:
  - (a) how the proposed ALCMI Research Project furthers ALCMI's mission;
  - (b) the name of each participating Collaborating Personnel and the name of one Collaborating Personnel who will serve as the liaison between the ALCMI Research Project and ALCMI;
  - (c) the name of the Collaborating Institution(s) that will participate in the ALCMI Research Project (each a "**Participating Institution**");
  - (d) the name of the Principal Investigator for each Participating Institution;
  - (e) the name of any Third Parties who will participate in the ALCMI Research Project;
  - (f) the Sponsor (if any) of the proposed ALCMI Research Project;
  - (g) the Research Protocol, which utilizes ALCMI's standardized systems and protocols;
  - (h) the Research Project Budget;
  - (i) whether ALCMI Funding or Third Party Funding is sought and, if so, how much; and
  - (j) whether Tissue and/or Data is requested from an ALCMI Repository.

March 8, 2011

- 3.3.2 ALCMI, in consultation with the SLB, will review each ALCMI Research Project Proposal to determine which projects to accept as ALCMI Research Projects and, for such accepted projects, for which ALCMI Research Projects ALCMI Funding will be provided.

**ARTICLE 4**  
**ALCMI Services and Obligations**

- 4.1 ALCMI Policies. ALCMI will, from time to time, develop and implement ALCMI Policies.
- 4.2 Collaborative Effort Membership. ALCMI, in consultation with the SLB, has the authority to accept new Collaborating Institutions into the Collaborative Effort, provided that all new Collaborating Institutions must (i) be recognized as exempt from taxation as organizations described in Section 501(c)(3) of the Internal Revenue Code and as other than private foundations under Section 509(a)(1) or 509(a)(2) of the Internal Revenue Code; and (ii) must sign a Master Collaboration Agreement in a form substantially similar to this Agreement; provided, however, that the Indemnification provisions may be modified to reflect the institutional limitations on liability coverage. ALCMI has the authority to terminate the participation of a Collaborating Institution from the Collaborative Effort in accordance with ALCMI Policies and Article 6 of this Agreement.
- 4.3 Soliciting Funding. ALCMI shall diligently seek to secure financial support for ALCMI Research Projects by:
- 4.3.1 Soliciting donations, grants, and other contributions to ALCMI to be used in furtherance of this Agreement;
  - 4.3.2 Presenting the Collaborating Institutions' capabilities in the Field and requesting Third Parties to provide Third Party Funding; and
  - 4.3.3 In its sole discretion, assisting Participating Institutions in selecting and engaging Third Parties to provide outside expertise, support, equipment, supervision or other assistance in connection with an ALCMI Research Project, for example a vendor or contract research organization.
- 4.4 ALCMI Research Project Funding. In the event that ALCMI is providing Funding for an ALCMI Research Project ("**ALCMI Funding**") on which is Institution is serving as a Participating Institution, ALCMI and Institution shall determine the payment schedule and timing for such funding in the corresponding Research Study Agreement.
- 4.5 Lead Negotiator. Unless and until ALCMI and Collaborating Institution(s) agree otherwise in writing, ALCMI, directly or through its legal counsel, shall act as the Lead Negotiator for all Research Study Agreements. As Lead Negotiator, ALCMI will negotiate the terms of Research Study Agreements consistent with the applicable Collaborating Institution(s)' policies or pre-existing obligations, of which the applicable Collaborating Institution(s) will use good faith efforts to keep ALCMI and its legal counsel reasonably apprised. The terms of any Research Study Agreements must be in

March 8, 2011

accordance with Applicable Law and are subject to the limitation in Section 5.9.6. For the purposes of clarity, failure to enter into a Research Study Agreement by a Collaborating Institution shall not constitute a breach of this Agreement.

- 4.5.1 Institution acknowledges that neither ALCMI nor ALCMI's legal counsel will, by acting as Lead Negotiator, be providing legal services to the Institution, and the Institution agrees to be responsible for engaging its own legal counsel to advise it with respect to all matters pertaining to the Collaborative Effort.
- 4.5.2 When acting as Lead Negotiator in negotiations with industry, ALCMI shall be entitled to reimbursement reasonable legal expenses related to negotiating that particular Research Study Agreement from the applicable Collaborating Institution(s) provided that the Parties agree to such payment terms in writing prior to ALCMI undertaking a negotiation for which Collaborating Institution will be charged.
- 4.5.3 Once an ALCMI Research Project Proposal has been approved by ALCMI, the Lead Negotiator will:
  - (a) Facilitate the execution of the terms of the Research Study Agreement by the Participating Institution(s) for the performance of the ALCMI Research Project;
  - (b) Facilitate and supervise the drafting of a Research Protocol if not already done; and
  - (c) Notify each Participating Institution of any changes to the applicable ALCMI Research Project once underway.
- 4.6 Personnel. Upon reasonable request and agreement between ALCMI and the applicable Collaborating Institution, ALCMI personnel may provide certain assistance to the Collaborating Institutions with respect to coordinating, managing, and overseeing ALCMI Research Projects.
- 4.7 ALCMI Repositories. ALCMI will bear all financial and administrative burdens, including contracting with third parties, associated with establishing and maintaining the ALCMI Repositories.
- 4.8 Results. ALCMI shall collect, maintain, and make all Results (including, without limitation, Interim Progress Reports, Data, Results, and Final Reports) available to the Collaborating Institutions, and other individuals approved by ALCMI in accordance with Authorizations (if applicable), applicable Research Study Agreements, applicable non-disclosure agreements, and Applicable Law.
- 4.9 Exclusions. Notwithstanding the foregoing, the Parties agree and acknowledge that ALCMI is not a Sponsor of any ALCMI Research Project.

**ARTICLE 5**  
**Collaborating Institution Participation**

- 5.1 Investigator Acknowledgement. All Collaborating Personnel serving as Investigators will be required to sign the acknowledgement set forth at Exhibit C to comply with and be subject to the terms of this Agreement.
- 5.2 Institution Representations. As of the Effective Date and throughout the Term of this Agreement, the Institution represents, warrants, and agrees that:
- 5.2.1 Each Collaborating Personnel serving as an Investigator possesses appropriate professional qualifications to conduct Research, possesses the necessary and appropriate professional qualifications in accordance with the terms of this Agreement, and will:
    - (a) possess a valid and unrestricted license to practice medicine pursuant to the laws of the state in which they reside or practice, or other academic or other suitable degree as reasonably necessary to conduct an ALCMI Research Project, for example, a Ph.D.;
    - (b) possess valid state and federal narcotics numbers, if a licensed physician engaged in the practice of medicine;
    - (c) hold a Human Subject Protection Certification as required by the NIH; and
    - (d) attest that they have not, at any time, been convicted of any state or federal crime that would constitute a bar to employment by the Institution or termination from the Institution's medical staff.
  - 5.2.2 This Agreement has been authorized by all requisite officials of the Institution and the Institution has the full legal right, interest, power and authority to enter into this Agreement and to perform its legal obligations hereunder;
  - 5.2.3 The execution and delivery of this Agreement and the performance of the Institution's respective obligations hereunder do not conflict with or violate any legal authority or obligation or with any contractual obligation of the Institution, its Collaborating Personnel, or, to the best knowledge of the Institution, any Collaborating Personnel who become affiliated with or employed by the Institution subsequent to the Effective Date of this Agreement;
  - 5.2.4 Neither the Institution nor any of its Collaborating Personnel, or agents or subcontractors that are involved in an ALCMI Research Project is: (1) excluded from participation in a Federal Health Care Program (as defined in 42 U.S.C. § 1320a-7b(f)) by the U.S. Department of Health and Human Services or any state government agency; (2) debarred from any federal or state procurement or nonprocurement program by a federal or state

government agency; or (3) designated a Specially Designated National or Blocked Person by the Office of Foreign Asset Control of the U.S. Department of Treasury;

5.2.5 The Institution has not been, at any time suspended, temporary excluded, or debarred from any federal program.

5.2.6 The Institution will promptly notify ALCMI of any proceeding to debar any Institution Collaborating Personnel of which the Institution becomes aware.

5.3 Research Study Agreements. For each approved ALCMI Research Project that a Participating Institution wishes to undertake, the Participating Institution must enter into an agreement, in a form to be agreed on, with ALCMI, any Sponsor, any Third Party providing Funding (if different than any Sponsor), and at the Participating Institution's election, the Principal Investigator (the "**Research Study Agreement**"); provided however, that when the Third Party Funding includes federal funding or support, the Research Agreement shall refer to the agreement between the Participating Institution serving as the primary grantee, any Participating Institutions serving as the subawardees, and ALCMI. The federal grant between the United States Government and the primary grantee shall be set forth in the grant agreement.

5.3.1 In all cases where an ALCMI Research Project involves multiple Participating Institutions, the Research Study Agreement shall clearly set forth the effect of termination of one or more Participating Institutions. In addition, in the case of a Clinical or Animal Research Project, the Research Study Agreement must be conditioned on IRB or IACUC, respectively, review and approval of the ALCMI Research Project as set forth in the Research Protocol. Furthermore, in the event that the ALCMI Research Project is a Clinical Research Project or otherwise involves significant potential risks and costs, a Collaborating Institution's agreement to provide indemnification for willful and knowing acts may be a prerequisite to being eligible to participate as a Participating Institution. The Research Study Agreement shall be treated as confidential to the extent consistent with Applicable Law. Each Research Study Agreement between ALCMI and a Participating Institution for any particular ALCMI Research Project shall be substantially similar to all other Research Study Agreements between ALCMI and other Participating Institutions for that ALCMI Research Project. Upon written request to ALCMI by an Institution that is a party to a Research Study Agreement, ALCMI shall provide to such Institution a redacted copy of any Research Study Agreements between ALCMI and another Institution for the same Research Study, wherein any information contained therein in regards to the site study budget shall be excluded.

(a) In the event of any inconsistency between this Agreement and any Research Study Agreement, the terms and conditions of the Research Study Agreement shall govern subject to Applicable Law.

- (b) In the event of any inconsistency between a Research Protocol for a Clinical Research Study and this Agreement or a Research Study Agreement, the Research Protocol shall control in all respects relevant to scientific matters and matters of Study subjects' care and safety. In all other respects this Agreement or the applicable Research Study Agreement shall control.
  - (c) In the event of any inconsistency between a Research Protocol for an Animal Research Study and this Agreement or a Research Study Agreement, the Research Protocol shall control in all respects relevant to scientific procedures, and in all other respects this Agreement and the Research Study Agreement shall control.
  - (d) In the event of any inconsistency between a Research Protocol for a Basic Research Study and this Agreement or a Research Study Agreement, the Research Protocol shall control in all respects relevant to scientific procedures, and in all other respects this Agreement and the Research Study Agreement shall control.
- 5.3.2 Each Collaborating Institution will keep ALCMI and its legal counsel reasonably apprised of any Third Party obligations or institutional policies bearing on the negotiation of the terms of any Research Study Agreement or on any ALCMI standardized Research Protocol terms. Each Collaborating Institution shall keep such information up to date on an ongoing basis. The Collaborating Institution shall not use such modified agreement form or Research Protocol unless and until ALCMI agrees to the modifications. If the parties are not able to agree on any such modification, the Collaborating Institution shall not participate in any ALCMI Research Project that would involve the use of such modified documents.
- 5.3.3 Each Participating Institution will be a signatory to the applicable Research Study Agreement.
- 5.3.4 Upon receipt from ALCMI (or its counsel) of a proposed Research Study Agreement for review, a Participating Institution shall approve or provide comments to ALCMI (or its counsel) as soon as reasonably practicable. In the event the Participating Institution responds after ten (10) days, it understands that this delay may necessitate that ALCMI exclude it from the ALCMI Research Project.
- 5.3.5 When a proposed Research Study Agreement uses the template approved by the Collaborating Institution and the SLB for Research Study Agreements without any material modifications, a Participating Institution shall not unreasonably withhold or delay its signature thereto. For the purposes of clarity, failure to enter into a Research Study Agreement by a Collaborating Institution shall not constitute a breach of this Agreement.

March 8, 2011

5.3.6 The Collaborating Institutions shall coordinate their efforts in reviewing a Research Study Agreement through their respective Principal Investigators, the liaison between the ALCMI Research Project and ALCMI, and ALCMI in order to streamline and expedite the negotiation with any Third Party.

5.4 Assets.

5.4.1 Each Collaborating Institution shall use all reasonable efforts and due diligence to obtain and furnish to ALCMI the Assets required by a Research Study Agreement.

5.4.2 Each Collaborating Institution shall collect Assets from Subjects in accordance with and the corresponding Research Study Agreement.

5.4.3 Prior to furnishing an Asset, each Collaborating Institution shall obtain from each Subject, as applicable, all necessary permissions, including, but not limited to, Authorization and Informed Consent (the "ICA") in a form approved by ALCMI and Collaborating Institution's IRB.

5.4.4 Each Collaborating Institution shall use reasonable efforts to furnish all Assets obtained by it to ALCMI by transmitting such Assets to the ALCMI Repository(ies) within ninety (90) days after such Asset is collected or developed.

5.4.5 Each Collaborating Institution shall, consistent with sound business practices, make reasonable efforts to cooperate with ALCMI to enable such Collaborating Institution to use its information technology infrastructure to furnish the Data to the ALCMI Repository(ies).

5.4.6 ALCMI and Collaborating Institutions that receive Assets shall use Assets solely in accordance with the applicable ICA.

5.5 Support for ALCMI Research Projects.

5.5.1 Each Collaborating Institution shall encourage its Collaborating Personnel to develop, and assist in the development of, Research Protocols for SLB consideration.

5.5.2 Each Collaborating Institution shall provide support to ALCMI Research Projects for which it is a Participating Institution as set forth in the applicable Research Study Agreement.

5.5.3 Upon execution of a separate written agreement, each Collaborating Institution may provide access to its equipment and facilities for ALCMI Research Projects (which access shall be subject to the availability of such equipment and facilities); provided, if the applicable ALCMI Research Project is not being conducted at or under the auspices of a Collaborating Institution, such hosting Collaborating Institution shall have the right to

charge for the use of such equipment and facilities (which charges shall not exceed its customary direct rate therefore plus 10% indirect rate for overhead). At the request of any other Collaborating Institution, a hosting Collaborating Institution shall advise such requesting Collaborating Institution and ALCMI of such costs and expenses within a reasonable time period after the request is made and, if requested to do so, such hosting Collaborating Institution shall furnish such facilities and equipment at such rates for the applicable ALCMI Research Project. If the Collaborating Institution provides access to its facilities or equipment, any Collaborating Personnel visiting from another Collaborating Institution agree to comply with all known or posted policies and procedures of the Collaborating Institution providing access.

- 5.6 Collaborating Personnel. From time to time, ALCMI may request the assistance of the Institution's Collaborating Personnel to participate in fundraising efforts on behalf of ALCMI. ALCMI understands the Collaborating Personnel can only provide assistance as consistent with the Collaborating Institution's policies. All donations and other funding arrangements arising out of any introduction(s) made by ALCMI or the Institution's Collaborating Personnel participating on ALCMI's behalf shall be made solely to ALCMI unless otherwise agreed to by ALCMI and the entity providing Funding. Both Parties agree to direct any such Third Parties to ALCMI or the Collaborating Institution, respectively, for such purposes.
- 5.7 Obligations of the Institution When Serving as a Participating Institution for ALCMI Research Projects. In addition to the other responsibilities set forth in this Agreement and in each Research Study Agreement executed by the Institution, the Institution, when serving as a Participating Institution, agrees to the following:
- 5.7.1 Each Participating Institution shall promptly, but in all cases within ten (10) business days, notify ALCMI in writing of any changed circumstances which would require amendments to this Agreement or Research Study Agreement;
  - 5.7.2 Each Participating Institution shall obtain and maintain approval of the ALCMI Research Project from all necessary regulatory bodies. Each Participating Institution and all of its Collaborating Personnel shall abide by Applicable Law in conducting any ALCMI Research Project, including by ensuring that its laboratories, equipment and other facilities are run in accordance with Applicable Law;
  - 5.7.3 Each Participating Institution shall arrange for any necessary committees to oversee the conduct of the ALCMI Research Project at the Institution and provide copies to ALCMI of any relevant notices or directives from such committees; and
  - 5.7.4 Each Participating Institution shall conduct the ALCMI Research Project in accordance with the Research Protocol.

5.7.5 Collaborating Personnel.

- (a) Each Participating Institution shall identify a Principal Investigator to oversee and direct the conduct of the ALCMI Research Project at that Participating Institution. The Principal Investigator shall identify any Sub-Investigators necessary to support the conduct of the ALCMI Research Project (collectively, with the Principal Investigator the “**Investigators**”). The Investigators, at all times, will be responsible for complying with investigator responsibilities as set forth in Applicable Law, and for conducting the ALCMI Research Project in accordance with the Research Protocol, this Agreement, and Applicable Law.
- (b) Each Participating Institution shall ensure that all participating Collaborating Personnel timely participate in any necessary orientation and training, if so required by ALCMI as set forth in a Research Study Agreement.

5.7.6 Funding.

- (a) Each Participating Institution shall ensure that ALCMI Funding for an ALCMI Research Project is used exclusively for (i) the activities and items set forth in the respective Research Project Budget or (ii) other costs pre-approved in writing by ALCMI. The Participating Institution acknowledges and agrees that it will not request ALCMI Funding in the Research Project Budget for any item or service related to an ALCMI Research Project for which it has received, or will likely receive, Third Party Funding.
- (b) In the event that ALCMI Funding will not cover the entire Research Project Budget, payment of ALCMI Funding is conditioned on the Participating Institution(s) obtaining Third Party Funding for the balance of the Research Project Budget or agreeing to cover the balance from its internal funds. The Participating Institution(s) shall be exclusively responsible for negotiating its budget with the Third Party Funding source; provided, however, that no such other funding agreements shall interfere with or diminish the obligations of Participating Institution or rights of ALCMI hereunder, and all fundraising efforts shall comply with Applicable Law.
- (c) In the event that there is Third Party Funding for an ALCMI Research Project, the Participating Institution(s) receiving such Third Party Funding shall report all such Third Party Funding to ALCMI in writing in conjunction with the reporting requirements set forth in Section 5.9.7. The Participating Institution(s) shall attempt to negotiate funding for ALCMI’s direct costs, including but not limited to, project management and costs associated with any use of ALCMI Repositories.

- (d) The Parties agree and acknowledge that any Funding received by a Participating Institution is not intended to reward past or induce future uses or referral of anyone's items or services.
- (e) It is ALCMI's normal and customary practice, absent extenuating circumstances documented in writing, to cap coverage of indirect and overhead expenses in a Research Project Budget at ten percent (10%) of direct costs when Funding is provided by ALCMI. In the event of Third Party Funding indirectly or directly provided by a Third Party to a Participating Institution, however, such Participating Institution may apply its customary indirect cost rate to said Third Party Funding in formulating the Research Project Budget.
- (f) It is ALCMI's normal and customary practice, absent extenuating circumstances documented in writing, not to provide Funding for any Billable item or services provided during the course of a Clinical Research Project. If ALCMI provides payment for a Billable item or service, the Participating Institution agrees that it will not bill or accept funding for the Billable item or service from a subject's Federal Health Care Program or private payor insurance.
- (g) The Parties acknowledge and agree that if a Principal Investigator is unable or unwilling to conduct an ALCMI Research Project at the Participating Institution, or wishes to modify the approach set forth in the Research Protocol, any Funding or other assistance provided by ALCMI will be conditioned on ALCMI's prior written consent to the change in Principal Investigator or Research Protocol.
- (h) In the event that ALCMI Funding exceeds the ALCMI-approved costs incurred by a Participating Institution in conducting an ALCMI Research Project, at the mutual election of the Participating Institution and ALCMI, the Participating Institution will return the Residual Balance or apply the Residual Balance to another ongoing or impending ALCMI Research Project at that Participating Institution. The Participating Institution agrees and acknowledges that it will not apply a Residual Balance to Research or any other activity without ALCMI's express written permission.

5.7.7 ALCMI Research Project Records and Reporting.

- (a) Each Participating Institution shall (i) maintain all Data resulting from the performance of an ALCMI Research Project, including all primary source documents and other related records pertaining to a particular ALCMI Research Project, but not including budget or other financial records or information, in a centralized file (each, a "**Research Project Record**"), (ii) make such Research Project Records available for review by ALCMI upon ALCMI's reasonable request at mutually agreeable times during

normal business hours, (iii) transmit copies of such Research Project Records to ALCMI and other Collaborating Institutions as may be required or requested, as consistent with Applicable Law or in furtherance of the goals of the Collaborative Effort, and (iv) maintain such Research Project Records for six (6) years from the end of the applicable ALCMI Research Project. In any audit or visit to Institution, ALCMI shall comply with Institution's applicable policies regarding access to medical records and/or information systems and other policies regarding security of Institution facilities.

- (b) Each Participating Institution shall submit written reports, in a template to be agreed on ("**Interim Progress Reports**"), detailing the progress of its work in connection with each ALCMI Research Project to ALCMI on a periodic basis (but no less frequently than semi-annually). Each Interim Progress Report shall also identify any Background Intellectual Property known to the Principal Investigator of each ALCMI Research Project and/or Third Party Intellectual Property known by Collaborating Personnel. The Parties acknowledge that any such assessment is being provided without due legal analysis as to whether the technology so identified, or any technology not so identified, is truly Background Intellectual Property or Third Party Intellectual Property. The good faith failure by ALCMI, any Collaborating Personnel, or any Collaborating Institution to accurately or completely identify all proprietary Background Intellectual Property or Third Party Intellectual Property shall not be deemed to be a breach of this Agreement.
- (c) Each Participating Institution shall submit a written report containing the final Results of an ALCMI Research Project obtained by the Participating Institution and copies of all written documentation evidencing the context for such Results ("**Final Report**") within ninety (90) days after said ALCMI Research Project is completed and/or terminated.

5.8 Special Requirements of the Institution When Serving as a Participating Institution for Bench Research. For each ALCMI Research Project that is Bench Research, a Participating Institution shall ensure access to proper facilities for conducting Bench Research, including facilities that meet the standards for conducting such Bench Research as set forth by the NIH.

5.9 Special Requirements of the Institution When Serving as a Participating Institution for Clinical Research. For each ALCMI Research Project that is a Clinical Research Project, each Participating Institution further agrees to the following:

- 5.9.1 The Participating Institution may serve as a Sponsor of the Clinical Research Project, if applicable. In the event that another Participating Institution or a Third Party is Sponsor, the Institution shall reasonably comply with its oversight in accordance with Institution's policies related to access to Institution's facilities and records.

- 5.9.2 The Participating Institution shall ensure oversight of the ALCMI Research Project by the Participating Institution's IRB and other necessary committees at the Institution, provide copies to ALCMI of any approval notices or other IRB directives, and notify ALCMI if at any time and for any reason IRB approval is withdrawn or revoked.
- 5.9.3 Prior to each Subject's participation in the ALCMI Research Project, the Participating Institution shall obtain from each Subject (i) either a signed ICA meeting the standards of Section 5.4.3 or a waiver of ICA by the Participating Institution's supervising IRB, and (ii) any other documents relating to the use and disclosure of PHI in connection with ALCMI Research Project that are required by the IRB that is reviewing and overseeing the ALCMI Research Project, and that are in conformity with the guidelines set forth in the IRB-approved Research Protocol.
- 5.9.4 The Participating Institution shall comply with all federal, state and local laws relating to the use or disclosure of individual health information, including PHI.
- 5.9.5 The Participating Institution shall enroll Subjects in the ALCMI Research Project in accordance with the Subject selection criteria as per the Research Protocol.
- 5.9.6 The Participating Institution shall comply with directives of the Participating Institution's IRB, and notify ALCMI to the extent any IRB directives vary from the Research Protocol.
- 5.9.7 The Participating Institution shall monitor for and report all Adverse Events to ALCMI, in writing, within twenty-four (24) hours of an Investigator making such report to the Institution's supervisory IRB and/or data safety monitoring board.
- 5.9.8 The Participating Institution shall conduct a review of all Protocol Line Items to determine which items and services are Billable and Non-Billable, and submit Billable charges for reimbursement in the usual course subject to Section 4.4. The Parties acknowledge and agree that each Participating Institution is solely responsible for determining which Protocol Line Items are Billable and for submitting such items for reimbursement.
- 5.9.9 The Participating Institution shall maintain all documents pertaining to each Subject's participation in an ALCMI Research Project in a centralized file (each, a "**Research Record**") and make such Research Records available for review by ALCMI upon ALCMI's reasonable request during normal business hours at mutually agreeable times, transmit copies of such Research Records to ALCMI or to other Collaborating Institutions as may be required or requested, as consistent with Applicable Law and in accordance with any ICAs or in furtherance of the goals of the Collaborative Effort, and maintain

March 8, 2011

such Research Records for a period of the longer of six (6) years after the conclusion of the ALCMI Research Project or the Term of the Innovation and Commercialization Agreement. The Research Record required by this Section 5.9.9 shall be maintained as part of the Research Project Record required by Section 5.7.7(a) of this Agreement.

5.10 Special Requirements for Animal Research. For each ALCMI Research Project that is an Animal Research Project, each Participating Institution further agrees to the following:

5.10.1 The Participating Institution shall, unless the Institution determines that the ALCMI Research Project is exempt from the requirement for an Institutional Animal Care and Use Committee (“**IACUC**”), have its appropriately constituted IACUC oversee, or arrange for an appropriately constituted IACUC to oversee, the conduct of the ALCMI Research Project at the Institution, provide copies to ALCMI of any approval notices or other IACUC directives related to the ALCMI Research Project, and notify ALCMI if at any time or for any reason IACUC approval is withdrawn or revoked.

5.10.2 The Participating Institution shall comply with directives of its IACUC, and notify ALCMI to the extent any directives vary from the Research Protocol.

5.10.3 The Participating Institution shall comply with Applicable Law governing Animal Research, including, but not limited to, the Animal Welfare Act, 7 U.S.C. §§ 2131-2156, and 21 C.F.R. Part 58 (the “**GLP Regulations**”); provided however, that if a Collaborating Institution cannot comply with GLP Regulations, such Collaborating Institution acknowledges and agrees that, in the event an ALCMI Research Project is intended to ultimately be referenced in a submission to the FDA, such Collaborating Institution may not be eligible to participate as a Participating Institution.

5.11 Subcontractor; Affiliates.

5.11.1 The Institution may engage a subcontractor to assist it in meeting its obligations under this Agreement. The Institution will cause any subcontractor to agree in a written contract to be bound by the terms and conditions that are materially similar to the applicable terms of this Agreement, except that the subcontractor will not have the right to further subcontract. Notwithstanding the foregoing, the Institution will retain primary and sole responsibility for carrying out its obligations hereunder, and shall not have the right to assign, transfer or convey its rights and obligations under this Agreement to any subcontractor.

5.11.2 Furthermore, the Parties hereby acknowledge that certain Collaborating Institutions may conduct certain of their ALCMI Research Project activities through one or more affiliates. Such affiliates shall be listed in the applicable ALCMI Research Project Proposal and Research Study Agreement. Each

Collaborating Institution shall be fully responsible for each of its affiliate(s) and such affiliate's compliance with all of the Collaborating Institution's obligations under this Agreement, and any applicable Research Study Agreement and the Innovation and Commercialization Agreement.

- 5.12 Institution Noncompliance. In the event the Institution is not able to meet or maintain any of its obligations under this Agreement or if there is a material change to any of its representations under Section 5.2, the Institution will promptly notify ALCMI in writing. Such written notification will include a description of the breach or material change, and how and by what reasonable date (not to exceed thirty (30) days) such breach or material change will be resolved. Failure to cure any such breach or material change as proposed or failure to provide written notice of such breach or material change to ALCMI will constitute a breach of this Agreement subject to termination according to Section 6.2.

## **ARTICLE 6** **Term and Termination**

- 6.1 Term. The term of this Agreement will commence on the Effective Date and will remain in effect for five (5) years unless terminated pursuant to this Article 6 (the "Initial Term"). The Agreement will automatically renew for successive five (5) year terms unless terminated pursuant to this Article 6 (each, an "Additional Term" and together with the Initial Term, the "Term").
- 6.2 Termination of this Agreement for Cause. This Agreement will terminate immediately if (a) a Party fails to meet the requirements of this Agreement and this breach is not cured within thirty (30) days of being notified of the breach; (b) a Party is disqualified or is debarred by the government from conducting Research; or (c) ALCMI or the Institution lose their status as organizations recognized as exempt from taxation under Section 501(c)(3) of the Internal Revenue Code. To acknowledge that fair and cooperative approaches to Intellectual Property are essential to the Collaborative Effort, this Agreement will also terminate immediately if the Parties terminate the Innovation and Commercialization Agreement.
- 6.3 Termination of this Agreement Upon the Advice of Counsel. In the event that either Party receives the legal advice of competent counsel stating that there is a substantial risk that this Agreement does not comply with Applicable Law, or that the terms and conditions of this Agreement might prevent the Institution from billing for services under any government or other third party reimbursement program, the Party will immediately notify the other Party of such advice in writing. Within ten (10) days of receipt of such written notice, the Parties will either:
- 6.3.1 amend this Agreement to eliminate the illegal or infeasible provision or activity and leave the Parties as nearly as possible in the same economic positions in which they would have been under the original terms of this Agreement; or

March 8, 2011

- 6.3.2 if the illegal or infeasible provision or activity is so fundamental that revision and continuation of this Agreement is not possible, or if the Parties are unable to agree upon a mutually agreeable amendment after good faith negotiation for thirty (30) days, then this Agreement will terminate.
- 6.4 Termination without Cause. Upon ninety (90) days prior written notice, either Party may terminate this Agreement without cause.
- 6.5 Termination of a Research Study Agreement. The termination of any agreement undertaken to effect the terms of this Agreement and entered into by the Parties, including, but not limited to, a Research Study Agreement, will not result in the termination of this Agreement, so long as the Parties otherwise continue to meet their obligations pursuant to this Agreement. In addition to any termination provisions set forth in a Research Study Agreement, each Research Study Agreement may be terminated (i) upon ninety (90) days written notice by either Party; (ii) immediately upon receipt of notice in the event of a material breach of the Research Study Agreement provided that the breaching Party is given notice of such breach and fails to cure such breach within thirty (30) days; and/or (iii) Participating Institution, its IRB, Principal Investigator, any regulatory body with authority, or ALCMI determine that the Research Study poses an unnecessary risk to the safety of the patients.
- 6.6 Effect of Termination of the Agreement.
  - 6.6.1 Upon termination of this Agreement, ALCMI shall remit to the Institution the pro rata share of any outstanding ALCMI Funding for services provided by the Institution or any of its Collaborating Personnel as of the date of the termination. In the event that the Institution has received an advance on ALCMI Funding for services not yet provided, it will return to ALCMI the pro rata share of any ALCMI Funding for items and services it has not completed as of the date of termination.
  - 6.6.2 Termination of this Agreement for any reason will not release either Party from any liability which has already accrued to the Party or which is attributable to any event occurring during the Term of this Agreement prior to such termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring during the Term of this Agreement prior to such termination.
  - 6.6.3 In the event of termination of this Agreement for any reason the Innovation and Commercialization Agreement shall survive unless otherwise terminated according to its terms and conditions. In the event this Agreement is terminated while Research Study Agreements continue, the applicable terms of this Agreement will continue to apply to those studies until those Research Study Agreements expire or are terminated.

- 6.6.4 Upon termination of this Agreement, ALCMI and any Third Party providing Third Party Funding will make a decision as to the continuation of this Agreement for the duration any ALCMI Research Project(s) in which the Institution is already a Participating Institution, and any ALCMI Research Project that has been approved to be conducted at or under the auspices of such Participating Institution, but has not been commenced. Upon any termination, the Institution shall return or destroy (as directed by the disclosing party) all Confidential Information and other materials, Data, and/or equipment furnished by ALCMI or any other Collaborating Institution(s), and return to the appropriate ALCMI Repository all unused Tissue; provided, however that Institution may retain one (1) copy of all Confidential Information for record keeping purposes.
- 6.6.5 For all Clinical Research Projects affected by termination of this Agreement, the Parties agree to work together and to follow the directives of all applicable supervising IRBs to protect the safety of the then-enrolled Subjects.
- 6.7 Remedies in Addition. The termination provisions of this Article 6 will not be exclusive, but rather will be in addition to any rights or remedies at law or in equity, or under this Agreement.

## **ARTICLE 7** **Insurance**

- 7.1 Institution Insurance. The Institution must, at its own cost, either procure insurance or establish a comprehensive actuarially funded self-insurance program with comprehensive general liability insurance coverage and healthcare professional liability coverage that covers claims related to Research during the Term of this Agreement and for at least five years thereafter for incidents occurring during the Term.
- 7.1.1 If the Institution elects to purchase insurance, it must procure this coverage through admitted or otherwise authorized carrier(s), and the Institution must notify ALCMI in writing within at least thirty (30) days prior to any cancellation, reduction in coverage, non-renewal of such policy, or any change in coverage that would render the Institution's insurance program inconsistent with the requirements of this Article 7. The Institution must provide evidence of such insurance and its renewal to ALCMI upon request.
- 7.1.2 If the Institution chooses to establish a self-insurance program, it must notify ALCMI in writing within at least thirty (30) days prior to any change in its self-insurance program that would render its insurance inconsistent with the requirements of this Article 7. The Institution must provide evidence of the funding of a self-insurance program to ALCMI upon request.
- 7.2 ALCMI Insurance. ALCMI shall, at its own expense, use diligent efforts to obtain within a reasonable time following the Effective Date, and shall maintain for the term of this Agreement and following termination to cover claims arising from the conduct of

Research Study Agreements comprehensive general liability insurance and if applicable, professional liability in a minimum amount of \$3,000,000/\$5,000,000. ALCMI shall provide proof of insurance to Institution after obtaining such insurance.

7.2.1. ALCMI must notify Institution in writing within at least thirty (30) days prior to any cancellation, reduction in coverage, non-renewal of such policy, or any change in coverage that would render ALCMI's insurance program inconsistent with the requirements of the Article 7. ALCMI must provide evidence of such insurance and its renewal to Institution upon request.

7.2.2. If ALCMI chooses to establish a self-insurance program it must notify Institution in writing within at least thirty (30) days prior to any change in its self-insurance program that would render its insurance inconsistent with the requirements of this Article 7. ALCMI must provide evidence of the funding of a self-insurance program to Institution upon request.

## **ARTICLE 8** **Confidentiality**

8.1 Generally. The basis for the Collaborative Effort is open exchange of Confidential Information among Collaborating Institutions and ALCMI. The Parties hereby acknowledge and understand that each may receive Confidential Information of one or more Collaborating Institution(s) or ALCMI directly from the Collaborating Institution(s) or through ALCMI or may receive Confidential Information of ALCMI from ALCMI or another Collaborating Institution, and despite any indirect means of transfer, the Parties agree to maintain and use the Confidential Information as set forth in this Article 8.

8.2 Confidential Information. Confidential Information disclosed hereunder shall remain confidential for a period of three (3) years from the date of disclosure. The receiving Party agrees that it will not use any Confidential Information received from a disclosing Party except for the purposes of performing this Agreement. The receiving Party agrees not to disclose any Confidential Information received from the disclosing Party to any Third Party without: (i) the prior written consent of the disclosing Party, unless such disclosure is required by law or as otherwise authorized by this Agreement.; and (ii) first obtaining a prior written agreement from the Third Party to hold and maintain the Confidential Information in confidence with at least the same degree of care that receiving party employs with respect to like Confidential Information, but at a minimum, no less than a reasonable standard of care. The receiving Party may only disclose Confidential Information to its employees or agents who are subject to obligations of confidentiality as least as restrictive as those contained herein. Each Party agrees to maintain and follow reasonable procedures to prevent unauthorized disclosure or use of the other Party's Confidential Information and to prevent it from becoming disclosed or being accessed by unauthorized persons. Where required by law, the receiving Party will provide prompt, advance written notice to the disclosing Party to allow the disclosing Party to seek a protective order or otherwise prevent disclosure of such Confidential

March 8, 2011

Information. Upon becoming aware of any unauthorized disclosure, loss or use of Confidential Information, the receiving Party will promptly, but in any event within three (3) business days, advise the disclosing Party of any unauthorized disclosure, loss, or use of Confidential Information. Upon any termination or expiration of this Agreement, each receiving Party agrees that all Confidential Information of the disclosing Party, whether in written, graphic, or other tangible form, will be returned to the disclosing Party upon written request. A single archival copy may be retained by the receiving Party hereunder to meet requirements of Applicable Law.

- 8.3 Third Party Confidential Information. The Parties acknowledge that ALCMI may hereafter be subject to non-disclosure or confidentiality agreements with entities providing Funding or other Third Parties pursuant to which ALCMI must protect or refrain from use of proprietary and/or confidential information which is the property of such entity providing Funding or other Third Party. In the event a Collaborating Institution has access to the proprietary and/or Confidential Information protected thereunder, the Collaborating Institution shall treat such information as if that Collaborating Institution were an original individual signatory thereto; provided, however, that the Collaborating Institution has reviewed and agreed to the terms and conditions of such non-disclosure or confidentiality agreement prior to disclosure of such proprietary and/or Confidential Information. Upon the direction of ALCMI, the Collaborating Institution shall not use information identified by ALCMI to be Third Party Confidential Information until such Collaborating Institution has executed the applicable confidentiality agreement with the entity providing Third Party Funding.
- 8.4 Exclusions. Confidential Information that is not PHI, as such term is defined by HIPAA, will not include information that: (i) is now or subsequently becomes generally available to the public through no wrongful act or omission of the receiving Party; (ii) the receiving Party can demonstrate in its written records to have had lawfully in its possession prior to disclosure to it by the disclosing Party; (iii) is independently developed by the receiving Party or individuals obligated to assign to the receiving Party without use of any Confidential Information received from the disclosing Party as evidenced by its written records; (iv) the receiving Party lawfully obtains without obligation of confidentiality from a Third Party who has the right to disclose; or (v) is required by law or regulation to be disclosed, provided that the receiving Party has provided prompt, advance written notice to the disclosing Party so as to enable the disclosing Party to seek a protective order or otherwise prevent disclosure of such Confidential Information. Institution may disclose the scope, parties to, and existence of this Agreement. Notwithstanding the foregoing, Institution may disclose Confidential Information to a Study subject's healthcare provider(s) or Third Party payor(s) to the extent reasonably necessary 1) to determine the appropriate medical treatment for such subject or 2) for the purpose of facilitating Third Party payment for such medical treatment.
- 8.5 Relief. Each Party agrees that any unauthorized disclosure, loss or use of Confidential Information may cause irreparable harm entitling the disclosing Party to seek injunctive relief, in addition to any other remedies available to it at law.

**ARTICLE 9**  
**Indemnification**

- 9.1 Generally. Each Party specifically reserves any common law right of indemnity and/or contribution which either Party may have against the other.
- 9.2 Indemnification of the Institution by ALCMI. Subject to Applicable Law, ALCMI shall indemnify, defend and hold harmless the Institution, Collaborating Personnel employed by or affiliated with the Institution, and the Institution's officers, directors, trustees, agents and employees and their respective successors, heirs and assigns ("**Institution Indemnitees**"), from and against: any and all actions, claims, damages, injury, liability, expenses or loss (including reasonable attorney's fees and costs) arising out of ALCMI's, its officers', directors', trustees', employees', agents', affiliates': (i) breach of this Agreement causing damages, injury, liability or loss sustained by the Institution Indemnitees; (ii) ALCMI's use or commercialization of Results, Assets or Intellectual Property received from a Collaborating Institution hereunder or a Collaborating Institution's Background Intellectual Property; and (iii) ALCMI's negligent or willful acts or omissions in performance of this Agreement, except to the extent such injury, loss, claims, or damages arise from the negligence or willful misconduct of the Institution Indemnitees; provided, however, that ALCMI shall only be obligated to indemnify the Institution Indemnitees to the extent that such Institution Indemnitees have agreed to indemnify the ALCMI Indemnitees pursuant to Section 9.3.
- 9.3 Indemnification of ALCMI by the Institution. Subject to Applicable Law, the Institution shall indemnify, defend and hold harmless ALCMI, its officers, directors, trustees, agents, employees, and affiliates ("**ALCMI Indemnitees**") from and against: any and all actions, claims, damages, injury, liability, expenses or loss (including reasonable attorney's fees and costs) arising out of the Institution's (i) breach of this Agreement causing damages, injury, liability or loss sustained by the ALCMI Indemnitees; (ii) Institution's negligent use or commercialization of Results, Assets, Intellectual Property developed in whole or in part by Institution hereunder or Institution Background Intellectual Property; and (iii) Institution's negligent acts or omissions in performance of this Agreement, except to the extent such injury, loss, claims, or damages arise from the negligence or willful misconduct of the ALCMI Indemnitees; provided, however, that Institution shall only be obligated to indemnify the ALCMI Indemnitees to the extent that such ALCMI Indemnitees have agreed to indemnify the Institution Indemnitees in their own Master Collaboration Agreement.
- 9.4 Subcontractors. Subject to Applicable Law, the Institution will be responsible for and will indemnify, defend and hold ALCMI harmless from any and all acts or omissions of subcontractors it engages to assist it with this Agreement.
- 9.5 Notification. Each Collaborating Institution represents that it has, prior to the date it signed this Agreement, notified ALCMI and the other Collaborating Institutions whether such Collaborating Institution has sovereign immunity under the laws of the state (or province) or country in which it is located, or if there is any statutory limitation on its indemnification hereunder, and upon the written request of ALCMI or other

March 8, 2011

Collaborating Institution, the applicable Collaborating Institution will provide the requesting party with notice of any changes in its sovereign immunity status or any changes in its state's (province's) statutory laws affecting its indemnification hereunder of which such Collaborating Institution has knowledge.

- 9.6 Duty to Cooperate. The Parties recognize that, during the term of this Agreement and for a period thereafter, certain risk management issues, legal issues, claims or actions may arise that involve or could potentially involve the Parties and their respective employees and agents. The Parties further recognize the importance of cooperating with each other in good faith when such issues, claims or actions arise. As such, the Parties hereby agree to cooperate in good faith to address such risk management and claims handling issues in a manner that strongly encourages full cooperation between the Parties.
- 9.7 Notice; Settlement. Each Party will notify the other Party promptly of any claim or liability for which indemnification is sought; provided, however, that any delay or failure to give such notice will not relieve the indemnifying Party of its obligations hereunder except to the extent that the indemnifying Party is actually and materially prejudiced by such delay or failure. The indemnitee(s) may, at its sole discretion and expense, participate and appear with the indemnifying Party in the defense of any claim or liability conducted by the indemnifying Party. The indemnifying Party may not settle any claim or liability without the prior written consent of the indemnitees, which consent shall not be unreasonably withheld or delayed.
- 9.8 Limitation on Liability. Except with respect to any indemnification obligations, in no event shall either Party be liable for any indirect, special or consequential damages, including but not limited to lost profits, savings or revenue, even if advised of the possibility of such damages.
- 9.9 **DISCLAIMER OF WARRANTIES. EACH PARTY ACKNOWLEDGES AND AGREES THAT NO OTHER PARTY NOR ANY OF THEIR PARENTS, SUBSIDIARIES OR AFFILIATES MAKES ANY WARRANTIES (EXPRESS, IMPLIED OR STATUTORY) OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY TISSUES, DATA, RESULTS, OR PROGRAM INVENTIONS.**

#### **ARTICLE 10** **Dispute Resolution**

- 10.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 10 if and when a dispute arises under this Agreement.
- 10.2 Resolution By Mutual Agreement. In the event of any dispute between the Parties to this Agreement, between Collaborating Institutions, or between Collaborating Institution(s)

and ALCMI relating to this Agreement or its subject matter, the parties to such dispute shall first seek to amicably resolve or settle the dispute in good faith by mutual agreement. If the parties have not reached a resolution or settlement within thirty (30) days of the receipt of written notice by one party to the other party or parties specifying the nature of the dispute and a request to negotiate a resolution (which period may be extended upon the mutual written consent of the parties), then such party may thereafter submit the dispute to mediation by written notice to the other party or parties.

10.3 Mediation. A party to a dispute relating to this Agreement or its subject matter may, by written notice to the other party or parties to the dispute, have any controversy arising out of or relating to this Agreement referred to mediation. The mediation shall be conducted by a single neutral Third Party skilled in mediation and the medical industry. The single mediator shall be chosen by the following procedure: (i) each party to the dispute shall choose three (3) possible mediators and simultaneously disclose their respective choices to the other party or parties; (ii) if a common mediator has been chosen by each party, then that mutually chosen mediator shall preside; (iii) if there is no common mediator among each party's three choices, then each party shall choose one mediator from the other party's three picks and the parties shall negotiate as to which one mediator presides. Any party may refuse to engage in or may terminate mediation at any time and for any reason whatsoever upon written notice to the other party or parties.

10.4 Interim Relief. Where a situation warrants, a party to a dispute arising under this Agreement or related to the subject matter of this Agreement may seek emergency relief, either within the context of an ongoing mediation or otherwise. If no mediation is then ongoing, the mediator selection process shall be compressed to five (5) business days. Where emergency relief is sought in the context of an ongoing mediation proceeding, the mediator may, at a party's request, order another party to the dispute to take any interim measures of protection that the mediator considers necessary in respect to the subject matter in dispute. A mediation proceeding for interim relief shall not exceed forty five (45) days from a petition for interim relief to the rendering of a decision. Any party to the dispute may request from a court of competent jurisdiction enforcement of a mediator's order granting interim relief. Where a mediator has not yet been appointed pursuant to Section 10.3, or where a mediator cannot be selected within the five (5) day period provided above or is otherwise not available, or where interim relief granted by mediators is not enforceable, a Party may seek interim relief directly from a court of competent jurisdiction.

## **ARTICLE 11** **Publication**

11.1 Publication. It is the intent of all Parties that the Results of the ALCMI Research Project(s) be published in a timely manner consistent with academic standards and with due consideration given to the protection of any intellectual property rights. It is also the intent of the Parties that if more than one Collaborating Institution contributes to the Results, any publication or presentation of those Results shall be published or made jointly by the contributing Collaborating Institutions. Accordingly, subject only to any additional requirements or limitations set forth in any separate agreement entered into by

any Collaborating Institution participating in a Sponsored Research Project with a Sponsor of such ALCMI Research Project (the "Sponsor Research Agreement"), each Collaborating Institution and the Principal Investigator shall have the right to publish or present the Results and conclusions from an ALCMI Research Project, provided, that: (i) such publication or presentation does not disclose any Confidential Information of ALCMI or of a Collaborating Institution without its consent; (ii) ALCMI has reviewed the intended publication or presentation as detailed below in Section 13.2; and (iii) with respect to Data from a Clinical Research Study, the Institution and its Principal Investigator comply with HIPAA. Where an ALCMI Research Project involves more than one Participating Institution, said Participating Institutions shall make in good faith all reasonable efforts to publish or present the Results and conclusions from said ALCMI Research Project jointly. If the Participating Institutions cannot reach an agreement on joint publication or presentation of the Results and conclusions within ninety (90) days of a proposal from one of the Participating Institutions regarding publication or presentation of said Results and conclusions and good faith efforts of the Participating Institutions to reach agreement on joint publication or presentation, each Participating Institution may, at its sole discretion, publish and/or present its own data and contribution to the Results and conclusions. The publication or presentation shall acknowledge ALCMI for its contributions, identify the Principal Investigator as a Collaborating Personnel, and acknowledge contributions of Collaborating Personnel from other Collaborating Institutions as appropriate.

11.2 Non-Disclosure. The Institution and Principal Investigator shall not disclose information containing Collaborative Intellectual Property to the public or any Third Party (other than a Collaborating Personnel of another Collaborating Institution, or patent counsel for the Institution) without providing ALCMI at least thirty (30) days to review and identify protect any Inventions or other Collaborative Intellectual Property therein and to identify and correct any inadvertent disclosure of ALCMI's Confidential Information or use of ALCMI's name which ALCMI, in its sole discretion in either case, considers inappropriate. The Institution and Principal Investigator will permit ALCMI to review all presentations, all manuscripts for publication, materials for website hosting or electronic distribution and other materials prior to any public disclosure or other disclosure that may constitute prior art under a subsection of 35 U.S.C. § 102 (or successor provision) or under the standards of the European Patent Office. The materials intended for disclosure shall be provided to the Innovation Management Director at least thirty (30) days prior to the intended date of disclosure.

11.3 Timeliness of Publications.

11.3.1 The Collaborating Institutions agree that, for any ALCMI Research Project involving more than one Participating Institution, no publication or presentation shall be made by a Participating Institution or its Collaborating Personnel until a presentation and/or publication is made jointly by all of the Participating Institutions participating in the ALCMI Research Project or the twelve (12) month anniversary of the end of the ALCMI Research Project, whichever is earlier.

11.3.2 The Collaborating Institutions agree that if Results from any ALCMI Research Project have not been submitted for publication within thirty (30) days of the earlier of the completion of ALCMI's review of such manuscript for publication in accordance with Section 11.2 or the termination of this Agreement, subject only to any additional limitations set forth in the applicable Research Study Agreement, ALCMI shall have the right to publish said Results after giving the Collaborating Institution sixty (60) days written notice of its intent to do so. Notwithstanding the foregoing, if a Collaborating Institution notifies ALCMI in writing, concurrently with furnishing Results to ALCMI, that such Results are not suitable for publication in a bona fide research journal, ALCMI agrees that it shall not authorize the publication of such Results unless and until the SLB determines in its independent judgment that such Results are suitable for publication in a bona fide research journal. ALCMI further agrees to defer such publication if, within the sixty-day notice period, or such longer period as may be needed to do additional experiments, the Collaborating Institution makes good faith efforts to prepare and submit Results to a bona fide research journal. Any publication by ALCMI shall cite all authors and their institutional affiliations according to academic standards for authorship unless such authors or institution(s) have notified ALCMI in writing during the aforesaid sixty-day notice period, that they do not wish to be named on any publication of such Results.

11.4 Types of Publications. Publication of Results of any ALCMI Research Project shall include, but not be limited to the publication of such Results in any journal, magazine, web site, newspaper article or any other written or broadcast form of conveyance including posters as are commonly used at scientific meetings and any oral presentation of such Results in any public forum or meeting.

11.5 Notice of Publication; Reprints. Each Collaborating Institution and its Principal Investigator shall provide ALCMI advance notice of the dates of any publications and shall furnish to ALCMI reprint copies of each published report of research sponsored, facilitated or administered in whole or in part by ALCMI.

## **ARTICLE 12** **Use of Name**

12.1 Generally. Neither Party shall use the name, logo or other symbols of the other Party or of another Collaborating Institution, or any of their personnel, officers, directors, employees, or students, for any marketing or promotional purposes without prior written consent of the other party(ies) whose name, logo or symbol is to be used, except as set forth in this Agreement, the applicable Research Study Agreement, or the Innovation and Commercialization Agreement. For any such proposed use, the party (whether ALCMI, the Collaborating Institution, or the Third Party) seeking consent shall provide a written request to the applicable party at least thirty (30) days prior to the proposed use(s), which such request shall include a copy of the materials intended for release, as well as the details of the information to be disclosed and the time, place and manner of such

March 8, 2011

disclosure. Once consent has been granted in writing for a particular use, such consent shall be deemed to apply to the use of such materials or substantially similar materials (whether such subsequent use is in the same or different media than the original use) by the applicable party, unless the consent otherwise explicitly provides. However, the approval to use such materials shall not apply if the reuse of the materials would constitute an express or implied endorsement of a party of any product or service without its prior written consent. Notwithstanding the foregoing, ALCMI shall have the right to use the Institution's name to announce its participation in any ALCMI Research Project for which it is a Participating Institution and to accurately disclose such participation on its respective website and in fundraising materials, presentation materials and other printed, electronic or other materials and orally. In addition, ALCMI shall have the right to immediately remove Collaborating Institution's name from ALCMI's website and other materials upon termination of this Agreement.

- 12.2 Announcements. Each Collaborating Institution and its Principal Investigator will cooperate with ALCMI in announcing any ALCMI Research Project(s), Project Inventions and/or Results. The text of any other publicity regarding the approval of the ALCMI Research Project(s), the discovery of any Project Invention and/or the announcement of any Results (other than the publication of such results in a scientific journal by the Principal Investigator) shall be subject to the mutual approval of ALCMI, the Sponsor of the ALCMI Research Project (if applicable), and the applicable Participating Collaborating Institution(s).
- 12.3 Advertising. The Collaborating Institution and its Principal Investigator shall, on a case-by-case basis, evaluate ALCMI's request for cooperation in connection with any written, photographic, filmed, broadcast or other forms of materials that ALCMI elects to produce to publicize any ALCMI Research Project(s) and/or the Collaboration and any decision to cooperate is at the Collaborating Institution's sole discretion.
- 12.4 Credit to ALCMI. Except for Research Study recruitment materials, any and all advertising, promotion, publication, presentation and/or exhibition relating to this Agreement or an ALCMI Research Project hereunder shall contain an appropriate credit recognizing ALCMI's contributions to and support of the ALCMI Research Project or the Collaboration, which credit shall appear in the section of any advertisement, promotion, publication, presentation and/or exhibition identifying the Principal Investigator's institutional affiliation, and shall appear in the same manner and placement as the Collaborating Institution's affiliation credit.

### **ARTICLE 13** **Miscellaneous**

- 13.1 Amendments. No amendment or change hereof or addition hereto will be effective or binding on either of the Parties hereto unless agreed to in writing by the authorized signatory of both Parties.
- 13.2 Assignment. Institution may not assign any of its rights or delegate any of its duties hereunder without the prior written consent of ALCMI, and any assignment in violation

March 8, 2011

of this provision shall be deemed null and void ab initio. No approved assignment shall diminish or obviate a Collaborating Institution's obligations under this agreement and the Collaborating Institution shall remain primarily liable for the acts and omissions of any such assignee.

- 13.3 Construction. The language in all parts of this Agreement will be in all cases construed as a whole according to its fair meaning and not strictly for or against any Party.
- 13.4 Execution. This Agreement may be executed in counterparts, each of which will be deemed an original and both of which together will constitute one instrument.
- 13.5 Force Majeure. No Party will lose any rights hereunder or be liable to another Party for damages or losses on account of failure of performance by a defaulting Party if the failure is occasioned by war, strike, fire, Act of God, earthquake, flood, lockout, acts of terrorism, embargo, governmental acts or orders or restrictions, failure of suppliers or third parties, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence, intentional conduct or misconduct of the nonperforming Party and the nonperforming Party has exerted reasonable efforts to avoid or remedy such force majeure; provided, however, the Party who is unable to perform will promptly provide written notice to the other Parties setting forth the nature of the delay or failure in performance and provide a date when full performance will be resumed. Any Party receiving such notice of delay or failure in performance will have the option to terminate this Agreement in accordance with Section 6.2.
- 13.6 Headings; Exhibits. The captions to the several Sections hereof are not a part of this Agreement, but are included merely for convenience of reference only and will not affect its meaning or interpretation. Any exhibit to this Agreement is expressly incorporated herein and has all binding effect. In the event of any inconsistency between this Agreement and any its exhibits or attachments, the terms and conditions of this Agreement shall govern.
- 13.7 Notices. All notices under this Agreement will be in writing and will be personally delivered or delivered by registered or certified mail, return receipt requested, postage prepaid or express courier. Any notice given by mail will be deemed on the date of receipt. Notices should be sent to:

To ALCMI:  
Mr. Steven Young  
Addario Lung Cancer Medical Institute  
1100 Industrial Road, Suite 1,  
San Carlos, CA 94070  
Fax: (650) 598-0282

To the Institution:  
**INSERT info**

March 8, 2011

- 13.8 Change in Laws; Severability. In the event either Party becomes aware of a change in Applicable Law that affects the legality or feasibility of this Agreement, such Party must promptly, and in any event within fifteen (15) days, notify the other Party after becoming aware of said change in Applicable Law, in accordance with the procedures set forth in Section 6.3 of this Agreement. In the event that any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Agreement will remain in full force and effect without that provision. In such event, the Parties will in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which will most nearly approximate the intent of the Parties.
- 13.9 Survival. Sections 2.5, 2.6, 5.7.7(a), 5.7.7(c), 5.9.9 and Articles 1, 6, 7, 8, 9, 10, 11, 12 and 13 of this Agreement will survive its Term and termination for as long as necessary to permit their full discharge.
- 13.10 Waiver. The waiver of or failure to enforce by any Party any breach of any term, covenant, or condition contained in this Agreement will not be deemed to be a waiver of any subsequent or similar breach of the same or any other term, covenant, representation, warranty, or condition.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement by their respective duly authorized representatives.

**ADDARIO LUNG CANCER MEDICAL  
INSTITUTE**

**INSTITUTION**

By: \_\_\_\_\_  
Print Name: Steven Young  
Title: President & Chief Operating Officer

By: \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**Exhibit A**

**Definitions**

Adverse Event	Any incident where the use of the Test Article or Test Method is suspected to have resulted in an adverse outcome for the Subject.
ALCMI	The Addario Lung Cancer Medical Institute, a non-profit corporation.
ALCMI Funding	Monies paid and/or in-kind support provided to a Participating Institution for its participation in an ALCMI Research Project by ALCMI.
ALCMI Indemnitees	Has the meaning set forth in <u>Section 9.3</u> of this Agreement.
ALCMI Policies	Policies and procedures adopted and implemented from time to time by ALCMI that are necessary for ALCMI to meet its obligations hereunder and to guide the Collaborative Effort.
ALCMI Repository(ies)	Collectively, the ALCMI Data Bank(s) and/or ALCMI Tissue Bank(s).
ALCMI Research Project	The Research work, Research Study, experiments, trials, or any other activities undertaken after approval of an ALCMI Research Project Proposal and pursuant to a Research Study Agreement. ALCMI Research Projects shall include, but not be limited to, Sponsored Research Projects.
ALCMI Research Project Proposal	A written proposal to conduct specific research activities submitted for review by the Scientific Leadership Board in accordance with this Agreement.
ALCMI Tissue Bank	The tissue tracking system and technology established and maintained by or for ALCMI in connection with the storage, distribution and tracking of Tissues, including the software, source and object code, interfaces, methods and other Intellectual Property relating to the structure, design, functionality, operation and framework of such tissue bank.
Animal Research and Animal Research Project	The use of animals in a Research Study for purposes of testing Test Articles or Test Methods to evaluate their safety and/or efficacy for use in humans.
Applicable Law	All federal, state and local laws and regulations relating to the conduct, funding, and/or results of an ALCMI Research Project, as may be enacted from time to time, and ALCMI Policies.
Approved ALCMI Research Project Proposal	An ALCMI Research Project Proposal approved by ALCMI and the Scientific Leadership Board in accordance with this Agreement.
Asset	Tissue and/or Data.
Authorization	The document or process evidencing a Subject's written agreement to the use and/or disclosure of her PHI in connection with a Clinical Research Project that contains the necessary elements of such a document or process, as set forth in HIPAA.

Background Intellectual Property	All patents and patent applications, compounds, and other intellectual property, owned or controlled by ALCMI or a Collaborating Institution that were created, invented or first reduced to practice by Collaborating Personnel either prior to the commencement of the applicable ALCMI Research Project or arising outside the scope of the applicable ALCMI Research Project, the use of which is necessary in the Research undertaken for the ALCMI Research Project, or necessary for the practice of a Project Invention or the results of the ALCMI Research Project or the use, manufacture or sale of a Project Invention (as is or will be defined in the Innovation and Commercialization Agreement) or Licensed Product (as is defined in the Innovation and Commercialization Agreement).
Bench Research	Research that does not involve animals and is not Clinical Research.
Billable	A Protocol Line Item that can be appropriately billed to a Federal Health Program or other Third Party payor.
Biological Material	Any and all tangible tissue, cells, cellular extract, fluid, protein, genetic material, matter, section, or laboratory animal derived from a biological source, and any derivative, part, progeny, and modification thereof and thereto, including synthetic nucleic acids, recombinant nucleic acids, recombinant cells, and transgenic or cloned animals.
Clinical Research or Clinical Research Project	An ALCMI Research Project involving Subjects.
Collaborating Institution	Any institution, including the undersigned Institution, that has signed a Master Collaboration Agreement.
Collaborating Personnel	Any qualified physician, scientist, or other personnel employed by or affiliated with a Collaborating Institution who works on an ALCMI Research Project.
Collaborative Effort	An innovative approach to biomedical research facilitated by ALCMI that facilitates interdisciplinary and inter-institution cooperation to accelerate scientific innovation pursuant to the Master Collaboration Agreement and any Research Study Agreement, and commercialization of scientific innovation pursuant to the Innovation and Commercialization Agreement entered into between ALCMI and Collaborating Institutions.

Confidential Information	Any and all information, technical and non-technical, written and oral, regardless of media or format, which is not published or otherwise in the public domain, including, for example: (i) information obtained or produced by a Collaborating Personnel in connection with the Collaborative Effort; (ii) Data or information concerning an ALCMI Research Project; (iii) Collaborative Intellectual Property and information concerning Collaborative Intellectual Property, (iv) any information or material in written, graphic or other tangible form or electronic form disclosed hereunder that is marked as “Confidential” at the time it is delivered to the receiving party, or (iv) any information disclosed orally which is identified as confidential or proprietary when disclosed and such disclosure of information is confirmed in writing by the disclosing party within 30 days after the date of initial oral disclosure.
Data	Any and all information (whether qualitative, quantitative, or otherwise) obtained or produced in performance of an ALCMI Research Project, including without limitation, PHI.
Effective Date	Has the meaning set forth in the Preamble to this Agreement.
FDA	The U.S. Food and Drug Administration.
Federal Health Care Program	Any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government or any state health care program, including the Medicaid programs, any program receiving funds under the Maternal and Child Health Services Block Grant program, Block Grants to states for Social Security services, and State Children’s Health Insurance Program.
Field	The diagnosis, prevention, and treatment of lung cancer.
Final Report	Has the meaning set forth in <u>Section 5.7.7(c)</u> of this Agreement.
HIPAA	The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder.
ICA	Authorization and Informed Consent.
Informed Consent	The document or process evidencing a Subject’s consent to enroll in a Clinical Research Project that contains the necessary elements of such a document or process, as set forth in Applicable Law and approved by an IRB.

Innovation and Commercialization Agreement	Means the agreement entered into by the Parties, pursuant to the MOU, to set forth the rights and responsibilities of the Parties with respect to Intellectual Property, Collaborative Intellectual Property (as is or will be defined in the Innovation and Commercialization Agreement), Background Intellectual Property, and commercialization of the same.
Innovation Management Director	A person designated by the Collaborating Institutions that are parties to a particular Research Study Agreement who shall oversee and make decisions and/or recommendations to such Collaborating Institutions regarding the Intellectual Property arising out of such Research Study Agreement and licensing thereof.
Institution	Has the meaning set forth in the Preamble to this Agreement.
Institution Indemnitees	Has the meaning set forth in <u>Section 9.2</u> .
Institutional Animal Care and Use Committee (“IACUC”)	A committee established or engaged by a Collaborating Institution to oversee Animal Research in accordance with and for the purposes expressed in Applicable Law.
Institutional Review Board (“IRB”)	An institutional review board established or engaged by a U.S. Collaborating Institution, or a Research Ethics Board of a Canadian Collaborating Institution, to oversee Clinical Research in accordance with and for the purposes expressed in Applicable Law and that Collaborating Institution’s policies.
Intellectual Property	Has the meaning set forth in the Innovation and Commercialization Agreement.
Interim Progress Report	Has the meaning set forth in <u>Section 5.7.7 (b)</u> .
Internal Revenue Code	The Internal Revenue Code of 1986, as amended.
Investigator	Has the meaning set forth in <u>Section 5.7.5(b)</u> of this Agreement.
Investigator Acknowledgement	Document, incorporated into the Research Study Agreement, documenting that the Investigator has read and understood this Agreement and agrees to be bound by its terms.
Lead Negotiator	The individual, whether affiliated with ALCMI or a Collaborating Institution, that will be the principal liaison with Third Parties for purposes of negotiating Research Study Agreements and Third Party Funding.
MOU	Has the meaning set forth in <u>Section 2.1</u> .
Non-Billable	The Protocol Line Items that cannot be billed to a Federal Health Program or third party payor.

Participating Institution	A Collaborating Institution undertaking an ALCMI Research Project in accordance with <u>Section 3.3.1(c)</u> .
Principal Investigator	The scientist or medical doctor employed or engaged by a Participating Institution who is either named as the Principal Investigator in an ALCMI Research Project Proposal approved by ALCMI and the Scientific Leadership Board in accordance with this Agreement, or who is otherwise by mutual agreement of ALCMI and such Participating Institution responsible for such Participating Institution's activities for a particular ALCMI Research Project.
Protected Health Information ("PHI")	Has the meaning set forth in HIPAA.
Protocol Line Item	The itemized items, services, tasks or other responsibilities required to be provided or performed pursuant to an ALCMI Research Project for which the Participating Institution seeks payment.
Research or Research Study	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A Research Study can involve Clinical Research, Animal Research or Bench Research.
Research Project Budget	The anticipated costs incurred by a Participating Collaborating Institution in conducting an ALCMI Research Project.
Research Project Record	The centralized file in which a Participating Collaborating Institution maintains (i) all Data resulting from the performance of a Research Project; (ii) all primary source documents; (iii) all agreements related to the Research Project; (iv) copies of institutional and regulatory approvals related to the Research Project; (v) all accountings of Payment received and spent; and (vi) any other related records pertaining to a particular Research Project, and as further defined in <u>Section 5.7.7(a)</u> of this Agreement.
Research Protocol	A formal and detailed description of an ALCMI Research Project, and a set of instructions for its execution.
Research Record	Has the meaning set forth in <u>Section 5.9.9</u> of this Agreement.
Research Study Agreement	Has the meaning set forth in <u>Section 5.3</u> of this Agreement.
Residual Balance	The funds remaining from Funding after an ALCMI Research Project is completed or terminated.
Results	All Data required to be compiled and delivered to ALCMI in accordance with the Research Project Agreement, but shall not include any ALCMI Repository(ies).
Scientific Leadership Board	The committee established by ALCMI to assist it in pursuing ALCMI's mission.

March 8, 2011

Serious Adverse Event	Has the meaning set forth in Applicable Law.
Sponsor	Has the meaning set forth in the regulations promulgated by the FDA.
Sub-Investigator	A Collaborating Personnel who serves as an Investigator but is not the Principal Investigator on an ALCMI Research Project.
Subject	A living human individual who is enrolled as a participant in a Clinical Research Project, and about whom an Investigator obtains Data through intervention or interaction with the individual, or a living human individual whose PHI is being reviewed or analyzed as part of an ALCMI Research Project.
Term	Has the meaning set forth in <u>Section 6.1</u> of this Agreement.
Tissue	The biological material or serum (1) obtained by a Collaborating Institution in connection with any ALCMI Research Project(s) or (2) obtained by ALCMI, independent of ALCMI Research Project(s), that ALCMI elects to contribute to the ALCMI Tissue Bank.
Test Article	Any drug, medical device, biologic (naturally occurring or recombinant), chemical (organic and inorganic), food additive, color additive, electronic product, or any other article subject to regulation by the FDA investigated or tested for any purpose in a Research Project.
Test Method	Any technique, method or process tested for any purpose in a Research Project.
Third Party	Any person or entity other than ALCMI, a Collaborating Institution, or Collaborating Personnel.
Third Party Funding	Monies paid and/or or in-kind support provided to a Participating Institution for its participation in an ALCMI Research Project from sources other than ALCMI.
Third Party Intellectual Property	Intellectual Property belonging solely to one or more Third Party(ies).

March 8, 2011

## Exhibit B

### MOU

THIS MEMORANDUM OF UNDERSTANDING (the “**MOU**”), effective as the effective date of the Master Collaboration Agreement (“**Effective Date:**”), is entered into by and between the Addario Lung Cancer Medical Institute (hereinafter “**ALCMI**”), a non-profit corporation, with a principal place of business at 1100 Industrial Road, Suite 1, San Carlos, CA 94070, and **INSTITUTION**, a not-for-profit \_\_\_\_\_ (**INSERT STATE**) corporation with a principal place of business at **ADDRESS**, (the “**Institution**” or “**NAME**” and together with ALCMI, collectively referred to as the “**Parties**” and each individually as a “**Party**”).

### BACKGROUND

**WHEREAS**, on the Effective Date, ALCMI and the Institution entered into a Master Collaborative Agreement which sets forth the Parties’ understanding as to the establishment of a network of academic medical centers, institutions, hospitals, hospital systems, and other institutional providers that wish to work with ALCMI and support its mission by conducting translational Research activities (each, a “**Collaborating Institution**”) through coordinated Research (“**ALCMI Research Project(s)**”); and

**WHEREAS**, as part of the Master Collaborative Agreement, the Parties have agreed to enter into an Innovation and Commercialization Agreement regarding the management of results and discoveries arising from ALCMI Research Projects performed by the Collaborating Institutions and Collaborating Personnel.

**NOW THEREFORE**, in consideration of the mutual covenants contained herein, the Parties, intending to be legally bound, hereby agree as follows:

1. Defined Terms. Capitalized words and expressions in this MOU will have the meanings set forth herein or in the Master Collaboration Agreement.
2. Negotiation of an Innovation and Commercialization Agreement. The Parties agree to negotiate in good faith the terms and provisions of the Innovation and Commercialization Agreement. If agreement cannot be reached between the Parties and the Innovation and Collaboration Agreement is not executed by the Parties within 180 days of the Effective Date, this MOU and the Master Collaboration Agreement between the Parties shall terminate immediately in accordance with the termination provisions set forth in the Master Collaboration Agreement.
3. Effective Date of the Innovation and Collaboration Agreement. The effective date of the Innovation and Collaboration Agreement shall be retroactive to the Effective Date.
4. ALCMI Research Project Participation. The Institution may participate in ALCMI Research Projects prior to the execution of the Innovation and Commercialization Agreement; provided, however, that such ALCMI Research Projects are subject to a Research Study Agreement executed prior to the 180 day negotiation window set forth in Section 2. In the event

March 8, 2011

that the Parties fail to negotiate an Innovation and Commercialization Agreement pursuant to Section 2 and the Master Collaboration Agreement terminates, any Research Study Agreement executed during the prior 180 day period shall also terminate in accordance with the termination provisions set forth in the Master Collaboration Agreement.

5. Termination of this MOU. This MOU shall commence on the Effective Date and continue until an Innovation and Commercialization and Agreement between the Parties is entered into or for 180 days, whichever is earlier. Either Party may terminate this MOU immediately in the event of a material breach of this MOU by the other Party. Upon termination of this MOU, the Master Collaboration Agreement between the Parties shall terminate immediately in accordance with the termination provisions set forth in the Master Collaboration Agreement.

6. Entire Agreement. This MOU and the Master Collaboration Agreement between the Parties constitute the full and complete agreement and all understandings and representations between the Parties pertaining to the subject matter referred to herein. This MOU can only be modified in writing by an instrument signed by duly authorized representatives of the respective Parties.

7. Severability. If any part, term or provision of the MOU shall be held void, illegal, unenforceable or in conflict with any law of a federal, state, or local government having jurisdiction over this MOU, the validity of the remaining provisions shall not be affected thereby and shall continue to have full force and effect.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement by their respective duly authorized representatives.

**ADDARIO LUNG CANCER MEDICAL  
INSTITUTE (ALCMI)**

**INSTITUTION**

By: \_\_\_\_\_

By: \_\_\_\_\_

Print Name: Steven Young  
Title: President & COO

Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_ +

March 8, 2011

**Exhibit C**

**Investigator Acknowledgement Template**

I, \_\_\_\_\_, hereby acknowledge the following with respect to the  
\_\_\_\_\_ research study (the "Research"):

1. I am serving as an Investigator at \_\_\_\_\_ "Institution" for the Research.
2. As an Investigator and employee of Institution, I shall comply with and be subject to the terms of the Master Collaboration Agreement between Addario Lung Cancer Medical Institute ("ALCMI") and Institution and the Research Study Agreement (collectively the "Agreements").
3. I shall conduct the Research as set forth in the Agreements and as described in the applicable Research protocol and in compliance with applicable laws and regulations.
4. I will timely participate in any necessary orientation and training, if so required by ALCMI as set forth in the Research Study Agreement.
5. I represent and warrant that I possess appropriate professional qualifications to conduct the Research, and will at all times during the Research:
  - a. possess a valid and unrestricted license to practice medicine pursuant to the laws of the state in which I practice, or other academic or other suitable degree as reasonably necessary to conduct the Research, for example, a Ph.D.;
  - b. possess valid state and federal narcotics numbers, if a licensed physician engaged in the practice of medicine; and
  - c. hold a Human Subject Protection Certification as required by the NIH.
6. I attest that I have not, at any time, been convicted of any state or federal crime that would constitute a bar to employment by Institution or removal from the Institution's medical staff.
7. To my knowledge, my obligations under this acknowledgement do not conflict with or violate any legal authority or obligation or with any contractual obligation of mine.
8. I have never been: (1) excluded from participation in a Federal Health Care Program (as defined in 42 U.S.C. § 1320a-7b(f)) by the U.S. Department of Health and Human Services or any state government agency; (2) debarred from any federal or state procurement or nonprocurement program by a federal or state government agency; or (3) designated a Specially Designated National or Blocked Person by the Office of Foreign Asset Control of the U.S. Department of Treasury
9. I shall participate in fundraising efforts for the Research on behalf of ALCMI consistent with the Institution's policies.
10. Signing this Acknowledgement does not create a fiduciary relationship between ALCMI and me.

Acknowledged and agreed to by:

\_\_\_\_\_  
\_\_\_\_\_

Printed Name

\_\_\_\_\_

Date