INSPIREMD, INC.

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 4, 2011

InspireMD, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	333-162168	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3 Menorat Hamaor St. Tel Aviv, Israel	67448
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 972-3-691-7691

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On October 4, 2011, InspireMD Ltd. (“ InspireMD ”), our wholly-owned subsidiary, entered into a clinical trial services agreement (the “ Clinical Trial Services Agreement ”) with Harvard Clinical Research Institute, Inc. (“ Harvard ”), pursuant to which Harvard will conduct a study entitled “MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction” (the “ Study ”) on behalf of InspireMD. InspireMD will pay Harvard an estimated fee of $6,994,456 for conducting the Study, subject to adjustment dependent upon changes in the scope and nature of the Study, which is expected to last 37 months, as well as other costs to be determined by the parties. The Clinical Trial Services Agreement will expire upon the final payment by InspireMD to Harvard for work performed by Harvard on the Study, unless earlier terminated pursuant to the terms therein. The Study is expected to enroll a total of 654 patients in 50 clinical sites in the United States and Europe. InspireMD is entering into a separate agreement with a third party to monitor and oversee the European clinical sites involved in the Study and to share the data from the European sites with Harvard.

InspireMD will have exclusive rights to the data produced by the Study and Harvard will transfer to InspireMD all rights to any intellectual property developed during the Study or relating to the Study or to InspireMD’s products being used during the Study. Harvard will, however, own all rights to the procedures, methodologies, computer programs and other know-how used and/or generated by Harvard in conducting analyses related to the Study. Harvard will not be responsible for any adverse reactions by any of the patient subjects taking part in the Study. All data produced by the Study will kept confidential by both parties, however, there are provisions by which an independent publications committee can publish results of the Study while providing InspireMD an opportunity to first publish and protect its intellectual property rights.

The foregoing summary of the Clinical Trial Services Agreement is not complete, and is qualified in its entirety by reference to the full text of the Clinical Trial Services Agreement that is attached as an exhibit to this Current Report on Form 8-K as Exhibit 10.1. Readers should review the Clinical Trial Services Agreement for a more complete understanding of the terms and conditions associated with this transaction.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
10.1	Clinical Trial Services Agreement, dated as of October 4, 2011, by and between InspireMD Ltd. and Harvard Clinical Research Institute, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INSPIREMD, INC.

Date: October 11, 2011

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
10.1	Clinical Trial Services Agreement, dated as of October 4, 2011, by and between InspireMD Ltd. and Harvard Clinical Research Institute, Inc.

CLINICAL TRIAL SERVICES AGREEMENT

This Agreement is effective **October 4, 2011** ("Effective Date") by and between:

Harvard Clinical Research Institute, Inc. ("HCRI")
930 Commonwealth Avenue
Boston, Massachusetts 02215

and

InspireMDLtd. ("InspireMD")
3 Menorat Hamor St.
Tel Aviv, Israel

"MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction"

WHEREAS , InspireMD (“Sponsor”) desires to engage HCRI for the purpose of providing Clinical Trial Services, as defined in Exhibit A to this Agreement, which will serve as the Scope of Work and budget for the Agreement, for the protocol for the “MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction” Study, which shall be developed by HCRI under a separate consulting agreement, with such Protocol being incorporated by reference; and

WHEREAS , HCRI and its professionals have experience in the development and administration of clinical trials of various Investigational Products; and

WHEREAS , the parties hereto deem it to be in their individual and mutual best interest to set forth the terms and conditions of their relationship herein; and

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

1. Definitions.

- “ **Clinical Sites** ” shall mean the hospitals and other medical institutions that are participating as clinical study sites in the Trial.
- “ **Clinical Trial Data** ” shall mean data provided to HCRI by the Clinical Sites during the Trial and may include, but shall not be limited to, information contained in case report forms, core laboratory data, if any, and clinical laboratory data, if any.
- “ **Clinical Trial Services** ” shall mean the Services described in Exhibit A to this Agreement, which shall serve as the Scope of Work and budget for this Agreement.
- “ **Investigational Product** ” shall mean the device, pharmaceutical, or biopharmaceutical product under investigation for the Trial.
- “ **Pre-Existing Intellectual Property** ” means all proprietary rights, including inventions, patents, patent applications, registered or unregisterd copyrights and works of authorship (whether or not published), trade secrets and other proprietary information relating to the Investigational Product and owned or licensed by Sponsor.
- “ **Principal Investigators** ” shall mean collectively the investigator who functions as overall principal investigator for the Trial and the investigators who function as principal investigators at the Clinical Sites.
- “ **Protocol** ” shall mean the investigational plan developed by HCRI and approved by Sponsor pursuant to the parties’ consulting agreement for performing the Trial.
- “ **Study** ” or “ **Trial** ” shall mean the clinical trial described in the Protocol.

2. Sponsor Liaison.

Sponsor shall designate a person who shall be Sponsor's primary liaison (the "Liaison") with HCRI for all purposes pursuant to this Agreement. The Liaison's duties shall include responding promptly and fully to all reasonable requests from HCRI. The Liaison may consult informally with HCRI's representatives, both in person and by telephone, regarding the Trial. All notices and approvals to be made by Sponsor pursuant to this Agreement shall be made by or through the Liaison, in accordance with Section 18(f) ("Notices"), and HCRI shall be entitled to look solely to the Liaison for such notices and approvals. The Liaison shall be **Eli Bar, Vice President of Research and Development** .

3. Primacy of Health Care Mission.

Sponsor acknowledges that the primary mission of HCRI is health care, education and the advancement of knowledge and, consequently, all Clinical Trial Services, (described in Exhibit A), provided by HCRI under this Agreement shall be performed in a manner best suited to carry out that mission. Furthermore, HCRI does not guarantee specific results of the Trial.

4. Data Ownership.

Sponsor shall have exclusive ownership rights to the Clinical Trial Data, as well as to the content of analyses and reports relating to the Trial which are delivered to Sponsor by HCRI. Sponsor shall be free to use the Clinical Trial Data and the content of such analyses and reports for its own business purposes, provided however that Sponsor agrees that it shall be solely liable for the content of the analyses or reports if it changes or otherwise modifies such analyses or reports in any way at any time from the form in which they were delivered to Sponsor. HCRI shall own all rights to the procedures, methodologies, computer programs, analytic tools, work papers, and know-how used and/or generated by HCRI in conducting such analyses relating to the Trial (collectively, "HCRI Know-How"). Sponsor agrees not to reproduce and/or disseminate such HCRI Know-How for its benefit or the benefit of any third party.

5. Compensation.

a. Compensation and Payment . In consideration for its services which shall be performed in a workmanlike manner in accordance with industry good practice standards, HCRI will receive remuneration equal to an estimated fee of ***$ $6,994,456*** **USD** , as detailed in Exhibit A. Additional costs described in Exhibit A as "TBD" shall be agreed to in writing by the parties prior to being incurred. Sponsor and HCRI expressly agree that such fee represents an estimate arrived upon in good faith and based on the parties' mutual understanding of the Scope of Work at the outset of this Agreement. Notwithstanding the conditions of Section 5(b) regarding changes in scope, it is hereby agreed that Sponsor shall not be required or obligated to pay any amount exceeding the aforesaid estimated amount including costs set forth in this Agreement unless agreed upon in writing between the parties and signed by their authorized signatory persons. This estimated fee will be invoiced according to the payment schedule provided in Exhibit B. Sponsor agrees to pay each undisputed invoice upon receipt. To the extent there is no good faith dispute as to the validity of the invoice, accounts not paid within forty-five (45) days of receipt thereof will be considered overdue. Overdue accounts will be charged 0.5% of the amount outstanding for each month that the invoice remains unpaid. Sponsor shall inform HCRI in writing of any disputed amounts invoiced within forty-five (45) days of receipt of invoice. Sponsor shall communicate such objection in a timely manner to HCRI after its discovery. Failure to inform HCRI as aforesaid shall not prejudice any of Sponsor's rights to disagree to any invoice at any time subject to statute of limitation.

b. Changes in Scope . Amounts paid by Sponsor under this Section 5 may be increased if the Scope of Work detailed in Exhibit A changes and if such amount increases the total contract value set forth above by more than $100,000 it should be pre approved in writing by Sponsor. If changes in scope are required, a Contract Change Order describing the modification to the Scope of Work and detailing the associated adjustment to the project costs will be issued by HCRI and agreed to in writing and signed by HCRI and Sponsor as soon as practicable. If requested by Sponsor in writing, or required by circumstances beyond either party's control, HCRI may continue performing services outside the Scope of Work (provided that the charge for such services shall not increase the total costs described in Exhibit A by more than $100,000 without Sponsor's written pre-approval) prior to the parties' execution of a Contract Change Order if interruption of performance would delay the Study or delivery of the Services contained in Exhibit A. Sponsor acknowledges that the timely continuation of Services is contingent upon Sponsor's prompt review and execution of proposed Contract Change Orders. Additionally, Sponsor acknowledges that certain adjustments to the estimated fee may be necessary during the term of this Agreement along with a detailed explanation of same; provided that the charge for such services shall not increase the total costs described in in Exhibit A by more than $100,000 without Sponsor's written pre-approval. HCRI shall provide Sponsor with prompt notice of any adjustment deemed necessary. Further, the parties shall review and address any dispute relating to all such adjustments.

6. Sponsor Obligations and Representations.

a. Representations Concerning the Investigational Product . Sponsor represents, warrants and agrees that the Investigational Product will be produced in accordance with all applicable laws and regulations. Sponsor further represents, warrants and agrees that appropriate federal and state government authorization has been or will be obtained for the use of the Investigational Product for the Trial.

b. Adverse Reactions . Sponsor agrees that HCRI is not responsible for the costs of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury to a participant in the Trial which result from participation in the Trial, except to the extent such costs arise directly from HCRI's gross negligence or reckless or intentional misconduct. This section is not intended to create any third-party contractual benefit for any participants or Clinical Sites in the Trial.

c. Immediate Notification of Adverse Reactions . Sponsor shall immediately transmit to HCRI any information regarding any Serious Adverse Events associated with the use of the Investigational Product. HCRI shall immediately transmit to Sponsor, or its designee, any information regarding previously unreported Serious Adverse Events experienced by participants in the Trial.

7. HCRI Obligations

a. HCRI shall carry out the Clinical Trial Services in the highest professional standards and in accordance with any law, regulation and rules including of the respective ethic committee.

b. In the event that HCRI receives a Notice of Inspection (a "Notice") from a regulatory agency which relates to the Project, HCRI shall: (a) notify Sponsor promptly of such Notice; (b) keep Sponsor informed of the progress of the inspection; and (c) provide to Sponsor a copy of any documents produced to the regulatory agency pursuant to such Notice.

c. Sponsor's authorized representatives may visit HCRI's site and facilities at reasonable times and with reasonable frequency during normal business hours and upon reasonable advance written notice, to observe the progress of the Clinical Trial Services. All such visits shall be subject to HCRI's restrictions and procedures relating to safety, security and protection of Confidential Information (as defined below), and in connection therewith, Sponsor's authorized representatives may be required to sign a confidentiality agreement, or an access agreement for special access-controlled areas. The terms of this Section are not intended to govern audits.

8. Confidentiality.

a. Confidential Information Defined . "Confidential Information" shall mean information provided by the party disclosing information ("Disclosing Party") to the other party ("Recipient") pursuant to this Agreement, or in anticipation hereof, which is preferably marked "Confidential" when disclosed or is otherwise treated as confidential by the Disclosing Party, except as excluded from this definition in Section 8(b). If not in tangible form, the Disclosing Party agrees to identify such information as confidential when disclosed and make reasonable efforts to confirm in writing the confidential nature of the information within thirty (30) days of such disclosure. Confidential Information shall include any reports or documents created by the Recipient that include, summarize, or refer to Confidential Information. Examples of Confidential Information include, but are not limited to, any information, data, or know-how relating to the Disclosing Party's business interests, products, procedures, pharmaceutical or device development efforts, trade secrets, information regarding marketing or pricing or vendors or suppliers, or other technological information. It is hereby acknowledged that all Clinical Trial Data and other materials prepared using the same or derived therefrom shall be treated as Confidential Information, and treatment of same will be in accordance with the Section entitled Publication.

b. Exclusions to Confidential Information . Confidential Information shall not include information or materials: (i) which was available to the public prior to the disclosure by the Disclosing Party; (ii) which were not acquired directly or indirectly from the Disclosing Party and which Recipient lawfully had in its possession prior to the Effective Date of this Agreement or any underlying confidentiality agreement between the parties, as demonstrated by proof in Recipient's records before the Effective Date; or (iii) which Recipient can demonstrate was developed by or for Recipient independently of the disclosure of Confidential Information by the Disclosing Party, as demonstrated by proof in Recipient's records.

c. Obligations of the Recipient . The Recipient of Confidential Information shall: (i) receive, maintain, and hold the Confidential Information in strict confidence and use at least the same level of care in protecting it that it uses with its own confidential material of a similar nature, but in no event less than reasonable care; (ii) take all reasonable steps necessary and appropriate to verify that Recipient's employees, subcontractors, officers, and/or agents treat the Confidential Information as confidential and to verify that such employees, subcontractors, officers, and/or agents are familiar with and abide by the terms of this Agreement; and (iii) not utilize Confidential Information, except as provided for herein, without first obtaining the Disclosing Party's written consent to such utilization. All obligations under this Section shall expire five (5) years after the termination of this Agreement.

d. Permitted Disclosure . Recipient may disclose Confidential Information only to the extent required by law or order of a court of competent jurisdiction, provided that Recipient promptly provide the Disclosing Party with advance notice of such imminent disclosure and provide assistance in obtaining an order to limit the scope of information being disclosed and to protect such Confidential Information using its best efforts. Such permitted disclosure shall not otherwise negate the obligation for Recipient to maintain the confidentiality of such information for any other purpose under this Agreement.

e. Retention and Destruction . At any time upon the request of the Disclosing Party, Recipient shall return or destroy all Confidential Information in its possession (and have an officer certify the scope of such return or destruction), including copies, and/or any other form or reproduction and/or description and/or analysis thereof made by Recipient. However, Recipient reserves the right to retain one (1) copy of such Confidential Information for purposes of verifying the Confidential Information that was provided pursuant to this Agreement. Recipient shall, at minimum, retain such copy of the Confidential Information in accordance with the time periods proscribed by applicable law.

f. Limited Delivery of Sponsor Confidential Information . The free dissemination of information is an important policy of HCRI. To minimize questions concerning the confidentiality of disclosures, trade secrets, or proprietary data or information, Sponsor agrees to limit to the extent possible the delivery of Sponsor Confidential Information to HCRI.

9. Publication; Publicity.

a Publication . In accordance with this subparagraph (a), HCRI shall have the right to publish or otherwise publicly disclose the results of the Study and other information gained in the course of this Agreement after the occurrence of the first of the following: (i) Sponsor's initial publication; (ii) written notification from Sponsor that an initial publication is no longer planned; (iii) one (1) year after termination of the Study or data lock. Prior to any publication, for a period of five (5) year following the date on which HCRI's right to publish arises, in the interest of protecting patent rights and Sponsor Confidential Information, HCRI shall submit manuscripts, abstracts and similar material generated by HCRI as a result of this Agreement ("Publications") to an independent publications committee, for review and comment at least forty-five (45) days prior to the planned publication or disclosure date. The independent publications committee will include representation by HCRI, Sponsor, and Principal Investigator(s). The procedure of treatment of such publication shall be determined by the publications committee. For purposes of publications pursuant to this Section, the results of the Study and other information gained in the course of this Agreement shall not be considered Sponsor's Confidential Information.

b Publicity . Neither party shall make any press release, presentation, advertising, promotional sales literature, or other promotional oral or written statements to the public that reference or allude to this Agreement, work performed under this Agreement, or the parties hereto, without the other party's prior written consent. HCRI shall, however, have the right to acknowledge Sponsor's support of the investigations under this Agreement in HCRI's brochure, web site, scientific publications, and other scientific communications. Sponsor shall be entitled to list HCRI and acknowledge HCRI's services to Sponsor hereunder at Sponsor's web site and other publications with notice to HCRI.

10. Inventions.

HCRI acknowledges Sponsor's ownership interest in all Pre-Existing Intellectual Property in the Investigational Product. HCRI agrees to take no action inconsistent with Sponsor's ownership of such Pre-Existing Intellectual Property.

HCRI hereby assigns, and agrees to assign, to Sponsor all right, title and interest HCRI may have in any invention, technology, trade secrets or know-how, data, information, works of authorship, indicia of sources, and other intellectual property rights, and any goodwill associated with the foregoing, resulting from HCRI's provision of the Clinical Trial Services hereunder and relating to the Investigational Product or to Sponsor's Confidential Information ("Sponsor Intellectual Property"), and HCRI agrees to assist Sponsor, at Sponsor's expense, in obtaining or extending protection thereto. At Sponsor's request and expense, HCRI shall execute all necessary documents to effectuate the assignment of any Sponsor Intellectual Property to Sponsor. Notwithstanding the foregoing, and as further described in Section 4 (Data Ownership), all other inventions or discoveries, innovations, suggestions or ideas (whether or not patentable or copyrightable) made or developed by HCRI during the term of this Agreement as a result of HCRI's general knowledge and unrelated to the Investigational Product or Sponsor's Confidential Information, shall be solely owned by HCRI.

Notwithstanding the foregoing but without derogating therefrom, the parties agree that nothing in this Agreement by implication or otherwise shall constitute a grant of rights to any Pre-Existing Intellectual Property, and that this Agreement is not intended to transfer any intellectual property rights that either party owned or in-licensed before entering this Agreement.

11. Indemnification.

a. Sponsor Indemnification . Sponsor shall indemnify, defend and hold harmless HCRI and its trustees, officers, medical and professional staff, employees, agents, subcontractors and their respective successors, heirs and assigns (the "HCRI Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) (collectively "Losses") incurred by, or imposed upon, an HCRI Indemnitee arising out of performance of the Study, infringement of intellectual property rights, the Investigational Product, or Sponsor's performance under this Agreement, except to the extent that such Losses are the direct result of an HCRI Indemnitee's gross negligence, or intentional misconduct.

b. HCRI Indemnification. HCRI shall indemnify, defend and hold harmless Sponsor and its trustees, directors, officers, employees and agents (collectively, the "Sponsor Indemnitees) from and against any Losses incurred by, or imposed upon, a Sponsor Indemnitee arising out of HCRI's gross negligence, wrongful act or omission, or willful malfeasance, except to the extent caused by a Sponsor Indemnitee's gross negligence or intentional misconduct.

c. Attorneys. The Indemnifying party agrees, at its own expense, to provide attorneys reasonably acceptable to the indemnitee to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought.

d Notice . Each party agrees to provide the other party with prompt written notice of any Losses which it has actual knowledge or a reasonable belief thereof. No party shall settle or pay any claim which may trigger an indemnification obligation without the indemnifying party's prior written consent.

e This Section shall survive expiration or termination of this Agreement.

12. Insurance.

a. Sponsor Insurance . Sponsor shall, at its sole cost and expense, procure and maintain product/completed operations liability insurance coverage as required by law in the country where the Study is conducted if local admitted insurance is required. Where no local admitted insurance is required the following shall apply:

Sponsor shall, at its sole cost and expense, procure and maintain product/completed operations liability insurance coverage in amounts of five million ($5,000,000) dollars each and every loss and in the aggregate for the period of insurance which names the HCRI Indemnitees as additional isureds. Such product/completed operations liability insurance shall include coverage for (i) clinical trials liability, and (ii) contractual liability. If Sponsor elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of two hundred fifty thousand ($250,000) dollars annual aggregate) such self-insurance program must be acceptable to HCRI and HCRI's insurance carrier. Such product/completed liability coverage will be maintained for three (3) years after the conclusion of the Study. The minimum amounts of insurance coverage required under this Section shall not be construed to create a limit of Sponsor's liability with respect to its indemnification under the preceding Section of this Agreement.

b. Proof of Insurance . Sponsor shall provide HCRI with written evidence of such insurance upon execution of this Agreement. Sponsor shall provide HCRI with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance.

c. Maintenance of Insurance . Sponsor shall maintain such comprehensive general liability insurance: (i) during the continuance of the Trial or the term of this Agreement, whichever is longer; and (ii) for a reasonable period after the period referred to in the preceding subpart (i), which in no event shall be less than six (6) years.

d. This Section shall survive expiration or termination of this Agreement.

13. Limitation of Liability and Remedies.

a. IN THE EVENT OF ANY MATERIAL BREACH, OMISSION, OR NEGLIGENCE BY HCRI IN THE PERFORMANCE OF ITS OBLIGATIONS UNDER THIS AGREEMENT, SPONSOR AGREES THAT ITS FIRST RECOURSE SHALL BE TO SEEK REPERFORMANCE BY HCRI OF THE SERVICES DETRIMENTALLY IMPACTED BY SUCH ERROR OR OMISSION AT THE SOLE COST AND EXPENSE OF HCRI. IN NO EVENT SHALL HCRI'S LIABILITY FOR SUCH MATERIAL BREACH OR OMISSION EXCEED 1.5 TIMES FEES PAID TO HCRI FOR THE AFFECTED SERVICE. SPONSOR FURTHER AGREES THAT HCRI SHALL NOT BE LIABLE TO SPONSOR FOR ANY SPECIAL, INDIRECT, EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING BUT NOT LIMITED TO ANY DAMAGES RESULTING FROM LOSS OF DATA, DELAY IN THE STUDY, LOSS OF PROFITS OR LOSS OF BUSINESS ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ANY PRODUCTS, SERVICES OR MATERIALS FURNISHED HEREUNDER, EVEN IF HCRI HAS BEEN ADVISED OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES.

b. EXCEPT AS EXPRESSLY STATED TO THE CONTRARY, THE LIMITATIONS STATED IN THIS SECTION'S SUBPARAGRAPH (a) SHALL APPLY WHETHER THE ASSERTED CLAIM, LIABILITY OR DAMAGES ARE BASED ON CONTRACT (INCLUDING BUT NOT LIMITED TO BREACH OF WARRANTY), TORT (INCLUDING BUT NOT LIMITED TO NEGLIGENCE AND STRICT LIABILITY) OR ANY OTHER LEGAL OR EQUITABLE GROUNDS, AND REGARDLESS OF WHETHER THE ASSERTED CLAIM, LIABILITY OR DAMAGES ARISE FROM PERSONAL INJURY, PROPERTY DAMAGE, ECONOMIC LOSS OR ANY OTHER KIND OF INJURY, LOSS OR DAMAGE. EACH OF SUCH LIMITATIONS IS INTENDED TO BE ENFORCEABLE REGARDLESS OF WHETHER ANY OTHER EXCLUSIVE OR NON-EXCLUSIVE REMEDY UNDER THIS AGREEMENT FAILS OF ITS ESSENTIAL PURPOSE. THE LIMITATIONS STATED IN THIS SECTION'S SUBPARAGRAPH (a) SHALL NOT APPLY TO CLAIMS, LIABILITIES OR DAMAGES WHICH ARE THE RESULT OF ARE A WILFULL MISCONDUCT BY HCRI.

c. Allocation of Risk . Sponsor acknowledges that the fees described in Exhibit A and the other economic terms of this Agreement and its Exhibits reflect the allocation of risks and the limitations of HCRI's liability hereunder.

14. Term; Termination.

a. Term . This Agreement shall continue in full force and effect until Sponsor has provided final payment to HCRI for the services actually provided and completed by HCRI pursuant to Exhibit A and any CCOs as described in Section 5(b). Termination of this Agreement, however, shall not relieve the obligations undertaken by the parties in Sections 4 (Data Ownership), 6 (Sponsor Obligations and Warranties), 8 (Confidentiality), 9 (Publication; Publicity), 10 (Inventions), 11 (Indemnification), 12 (Insurance), and 13 (Limitation of Liability and Remedies), 16 (Non-Solicitation; Financial Interest in Sponsor), and 19 (Miscellaneous).

b. Termination without Cause . Either party may terminate this Agreement without cause by providing sixty (60) days written notice to the other party.

c. Termination for Bankruptcy/Insolvency . Either party may immediately terminate this Agreement if the other party files a petition in bankruptcy or is adjudicated as bankrupt or insolvent, or makes an assignment for the benefit of creditors, or an arrangement pursuant to any bankruptcy law, or if the other party discontinues its business or if a receiver is appointed for the other party or the other party's business who is not discharged within sixty (60) days.

d. Termination for Cause . Either party may terminate this Agreement for cause after providing the breaching party with thirty (30) days' written notice of the breach and the opportunity to cure the breach during such period.

e. Effect of Termination . Upon termination of this Agreement for any reason, Sponsor shall promptly pay HCRI on a time and materials basis for all work performed and expenses incurred through the effective date of termination including, without limitation, amounts due for closeout costs and non-cancelable commitments incurred through that date, if such costs exceed the amounts previously paid under this Agreement.

15. Compliance with Laws and Policies.

a. Compliance with Law . Sponsor and HCRI shall comply with all applicable federal, state and local laws, regulations and guidelines, including but not limited to any such laws, regulations or guidelines concerning human subject research.

b. Adherence to Policies . Sponsor recognizes that in performing services under this Agreement, HCRI is bound by and all rights of Sponsor will be subject to the Faculty of Medicine of Harvard University's Faculty Policies on Integrity in Science (www.hms.harvard.edu/integrity/).

c. HIPAA and Data Protection. The parties acknowledge that HCRI is a non-covered entity under the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). To the extent applicable, HCRI shall comply with all applicable international, federal and state laws and regulations governing patient privacy and confidentiality of health information, including without limitation HIPAA, and the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH Act") and their implementing regulations. As applicable, HCRI shall take all actions necessary to comply with such laws and regulations, including, without limitation, agreeing to amend this Agreement as necessary for compliance.

16. Non-Solicitation; Financial Interest in Sponsor.

a. Sponsor shall not solicit for employment or employ, at any time during the term of this Agreement, and for a period of one (1) year thereafter, any subcontractor performing services or person employed by HCRI at any time during the term hereof, without the prior written consent of HCRI. If Sponsor employs a staff member of HCRI without HCRI's prior written consent, Sponsor agrees to pay a fee of 200% of the individual's salary or expected compensation for the first year of service.

b. Neither Sponsor, nor any affiliate or subsidiary of Sponsor, shall grant, issue or provide, or agree to grant, issue or provide, any financial interest, including any consulting or other fee, stock, or other equity interest, to any person employed by HCRI or any immediate family member of any person employed by HCRI, without the prior written consent of the President and Chief Executive Officer of HCRI.

17. Arbitration.

a. The parties shall settle by arbitration any controversy or claim between them arising directly or indirectly under this Agreement, whether based on contract, tort, fraud, misrepresentation or other legal theory, and whether or not arbitration has been expressly referenced elsewhere in a particular section or a particular subsection of this Agreement. The arbitration shall occur in Boston, Massachusetts under the then current rules and supervision of the American Arbitration Association. If the dispute involves a claim for money in the amount of five hundred thousand ($500,000) dollars or less and does not involve any claims relating to ownership, use, or disclosure of intellectual property, the arbitration shall be before a single arbitrator whom the parties shall select from a panel of persons knowledgeable in the therapeutic area addressed by the Trial and clinical research; otherwise, the arbitration shall be before three arbitrators, one selected by Sponsor, one selected by HCRI, and the third selected by the two arbitrators so selected. The arbitrator or arbitrators shall not have the power to award punitive or exemplary damages. The decision and award of the arbitrator or arbitrators shall be final and binding and the award rendered may be entered in any court having competent jurisdiction. The parties shall each pay their own attorneys' fees associated with the arbitration, and shall pay the other costs and expenses of the arbitration as the rules of the American Arbitration Association or the arbitrator provide.

b. Any party may request arbitration to resolve any controversy or claim, between them, as provided above, by written notice to the other proposing an arbitrator. The other party receiving such written notice shall have thirty (30) days in which to agree with such choice of arbitrator or, if three arbitrators are required, to propose its arbitrator.

18. Force Majeure.

a. Neither party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to be unable to perform its obligations under this Agreement, and which it has been unable to overcome by the exercise of due diligence.

b. In the event of the occurrence of such a force majeure event, the party unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

19. Miscellaneous.

a. Independent Contractors . For the purposes of this Agreement, the parties shall be deemed to be independent contractors of one another and not employees or agents of the other.

b. Entire Agreement and Modification . This Agreement and its Exhibits constitute the entire agreement between the parties, and all prior negotiations, representations, agreements and understandings are superseded hereby. No agreements amending, altering or supplementing the terms hereof may be made except by means of a written document signed by a duly authorized representative of each party.

c. Use of Headings . The headings in this Agreement are for convenience of reference only and shall not alter or otherwise affect the meaning hereof.

d. Severability and Waiver . The invalidity or unenforceability of any term or provision hereof shall not affect the validity or enforceability of any other term or provision hereof. Failure of either party to enforce a right under this Agreement shall not constitute a waiver of that right or the ability to later assert that right.

e. Assignment . This Agreement shall be binding upon and inure to the benefit of each of the parties hereto and their successors and permitted assigns; provided, however, that this Agreement may not be assigned by either party without the prior written approval of the other party.

f. Notices . Any notice or other communication, including invoices, required or permitted by this Agreement will be in writing and will be considered given as of the date it is received by the addressee. Such notice will be given to the parties at these addresses:

To Sponsor:
InspireMD
3 Menorat Hamor St.
Tel Aviv, Israel
Attention: Eli Bar, VP R & D

Phone: +972-3-6917691
Fax: +972-3-6917692
Email: elib@inspire-md.com

To HCRI:
Harvard Clinical Research Institute
930 Commonwealth Avenue, 3rd Floor
Boston, MA 02215
Attention: Contracts Department

Phone: 617-307-5486
Fax: 617-307-5605
Email: Kevin.Hart@hcri.harvard.edu

Upon receipt of invoice Sponsor will provide written confirmation of same to Claudia Thum, by email at Claudia.Thum@hcri.harvard.edu

g. Governing Law and Jurisdiction/Venue . This Agreement shall be governed by and construed in accordance with the laws of The Commonwealth of Massachusetts. The parties hereto agree that all actions or proceedings arising in connection with this Agreement, which are unresolved by the means proscribed in Section 16, shall be tried and litigated exclusively in the State and Federal courts located in Suffolk County, in the Commonwealth of Massachusetts. The aforementioned choice of venue is intended by the parties to be mandatory and not permissive in nature, thereby precluding the possibility of litigation between the parties with respect to or arising out of this Agreement in any jurisdiction other than that specified in this Section. Each party agrees that the State and Federal courts located in Suffolk County, Commonwealth of Massachusetts, shall have in personam jurisdiction and venue over each of them for the purpose of litigating any dispute, controversy, or proceeding arising out of or related to this Agreement.

IN WITNESS WHEREOF , the parties have caused this Agreement to be executed by their duly authorized representatives in two (2) counterparts, each of which shall be considered one and the same original.

InspireMD

By: /s/ Asher Holzer

Name: Asher Holzer

Title: President

Date: October 5, 2011

By: /s/ Ofir Paz

Name: Ofir Paz

Title: CEO

Date: October 5, 2011

Harvard Clinical Research Institute, Inc.

By: /s/ J. Spen cer Goldsmith

Name: J. Spen cer Goldsmith

Title: Pres i dent

Date: October 4, 2011

EXHIBIT A

Project Parameters:

The Scope of Work is summarized below. Should there be a change in the project assumptions or Scope of Work outlined herein, HCRI reserves the right to reflect such modifications with a revision of fees.

Number of Patients Enrolled	654
Number of Clinical Sites	50 Sites (16 US, 34 OUS)
Study Duration:	
Planning & Start Up Period	38 Weeks
Enrollment Period	61 Weeks
Follow-Up Period (Including LTFU)	52 Weeks
Database Closure & Reporting Period	8 Weeks
Total Project Period	159 Weeks (37 Months)
eCRF Programming:	
Standard eCRF pages to be Programmed	14
Event eCRF pages to be Programmed	2
ECG eCRF pages to be Programmed	1
Angio Core Lab eCRF pages to be Programmed	2
eCRF Randomization page to be Programmed	1
Total eCRF pages to be Programmed	20
Total Number of Edit Checks	200
Data Processing:	
Standard CRF forms to be processed per patient	37
Event CRF forms to be processed per event	4
ECG CRF forms to be processed per patient	2
Angio Core Lab CRF forms to be processed per patient	2
Randomization forms to be processed per patient	1
Total Number of CRF forms to be processed per patient	46
Total Number of CRF forms to be processed	27,403
Query Rate / Total Estimated Queries	10%/2,740
Electronic Data Capture:	
Total Number of Users	110
Help Desk (hours per day/days per week)	24/7
Total Number of Datapoints processed	274,030
Statistical Reports:	
Primary Endpoint Statistical Report – 12 Month (# of TLGs)	1 (25, 2, 8)
Interim Statistical Report (# of TLGs)	1 (8, 1, 4)

Annual Report (# of TLGs)	1 (5, 1, 4)
Total Number of Statistical Reports	3
Frequency of Study Metric Reports	Weekly
Core Laboratories (Angio)	Entered
Safety Reports:	
Regulatory Reports (Cumulative)	1 Report/Month during Enrollment and Follow-up
Regulatory Reports (Weekly)	1 Report/Week during Enrollment and Follow-up
CEC & SAE Processing:	
CEC Events Adjudicated	
Total CEC Events	131 (20%)
SAEs Processed	
Total SAEs Processed	229 (35%)
Source Document Tracking:	
Source Documents per Event	5
Number of Events	360
Total Source Documents to be Tracked	1,800
Medical Coding:	
Adverse Event Coding	10 Per Patient
Concomitant Medication (ConMed) Coding	10 Per Patient
Data Monitoring Committee (DMC) Services:	
Estimated Number of DMC Meetings	4
Total Number of DMC Reports (# of Tables and Graphs for each)	3 (5, 2)
ECG Core Lab:	
2 ECGs to be read per patient (Pre-Procedure, Hospital discharge, events estimated 10% of patients)	1,373 Total Reads

Clinical Site Monitoring:

US Site Monitoring	# of Visits Per Site	# of Number Sites	Total Visits Per Site
Qualification/ Initiation Visits*	1	16	16
Interim Visits	5	16	80
Closeout Visits	1	16	16
Total Visits			**112**

* At the request of the Sponsor, US Clinical Sites will have a combination qualification and initiation visit. This is only possible when the sites are known to HCRI or InspireMD.

**For OUS Clinical Sites, at request of the Sponsor, no qualification visits will be performed. This is only possible when the sites are known to the OUS Vendor or InspireMD. In case sites are selected that are unknown to the OUS Vendor, a site call must be made to obtain the relevant start up information.

Tasks & Responsibilities

HCRI's Roles & Responsibilities	
PROJECT MANAGEMENT	
Develop and manage HCRI's study timelines	Yes
Manage completion of HCRI's study deliverables	Yes
Participate in / coordinate teleconferences	Yes
Schedule and attend Sponsor Meetings	Yes
Investigator Meetings (attendance)	Yes
Coordinate core lab(s)	Yes
Coordinate printing of protocol (used in Manual of Operations; Printing costs not included)	N/A
Case Report Forms (CRFs)	
Print CRFs/guidelines (via subcontract, billed to sponsor as a pass-through cost)	N/A
Ship CRFs/guidelines (billed to sponsor as a pass-through cost)	N/A
Coordinate distribution, tracking & re-ordering of CRFs	N/A
CLINICAL DOCUMENT DEVELOPMENT	
Protocol (contracted separately)	
Perform literature review	N/A
Develop protocol summary	N/A
Develop full protocol (2 drafts)	N/A
Draft protocol amendments	N/A
Biostatistician input into clinical trial protocol	N/A
Review protocol only (by project team during Planning phase)	Yes
DATA MANAGEMENT ACTIVITIES / ELECTRONIC DATA CAPTURE (EDC)	
Develop data management plan (DMP) (up to 3 drafts)	Yes
Database development	
Edit checks development	Yes
eCRF and database specifications	Yes
eCRF and database build	Yes
Edit check mock data testing	Yes
Edit check test plan	Yes
Specify, build, test and implement edit checks	Yes
Develop export specifications	Yes
Case Report Forms (CRFs)	
Develop eCRFs (3 drafts)	Yes

HCRI's Roles & Responsibilities	
Creation of annotated eCRFs	Yes
Develop eCRF completion guidelines	Yes
Prepare training materials for EDC system	Yes
Train PIs and end users on EDC system	Yes
Maintain electronic study file library	Yes
Study portal setup	Yes
Site assessments	Yes
Facilitate database hosting	Yes
Facilitate help desk and support	Yes
Facilitate system change control	Yes
Tracking	Yes
Data entry	N/A
Data cleaning	Yes
Medical coding	
Adverse events	Yes
Concomitant medications	Yes
Database audit	N/A
Facilitate closeout and database decommission	Yes
MEDICAL OVERSIGHT	
Participation by physician in regulatory agency meeting	No
Protocol and CRF review by physician	Yes
Oversight of trial conduct by physician	Yes
CLINICAL EVENTS COMMITTEE (CEC)	
Event review, coding and narration of endpoint events	Yes
CEC review and adjudication of endpoint events	Yes
Development and drafting of CEC Manual of Operations for sponsor review	Yes
Produce and distribute meeting minutes to sponsor	Yes
CEC management and meeting coordination	Yes
Limited querying for data related to review and adjudication of endpoint events	Yes
Contracting with CEC physicians and COI management	Yes
CLINICAL SAFETY	
SAE review/processing with narratives	Yes
Notification of SAE to Sponsor	Yes
Safety regulatory reporting (MedWatch/CIOMS)	
Submission of SAE regulatory report to sponsor	Yes
Submission of SAE regulatory report to FDA or other regulatory authorities	No

HCRI's Roles & Responsibilities	
Distribution of SAE regulatory report to sites	No
Medical Monitoring	Yes
DATA MONITORING COMMITTEE (DMC)	
DMC Management	Yes
STATISTICAL ANALYSIS	
Write statistical section of protocol (including sample size)	N/A (under separate agreement)
Statistical analysis plan (SAP) and definition of data displays	Yes
Design and implement randomization scheme	Yes
Program statistical tables, listings, and graphs	Yes
Develop export specifications	Yes
REPORTS	
Provide 1 interim report (2 drafts)	Yes
Provide 1 primary endpoint report (2 drafts) at 12 Months	Yes
Provide 3 DMC reports	Yes
Provide 1 annual safety report	Yes
Provide medical writing	Yes
Exploratory analyses (to be billed as out of scope, if requested)	Yes
ARCHIVING	
Organize and index all necessary study-related documents to be archived	Yes
Arrange archiving of the study-related documents	Yes
Box and transfer documents to archive	Yes
SITE MANAGEMENT/SITE MONITORING ACTIVITIES (US Sites Only)	
Investigator selection in collaboration with the Sponsor	Yes
Develop informed consent form (ICF) template in English	Yes
Conduct on-site qualifying site assessment visits	No
Collect/review regulatory documents	Yes
Assist sites with IRB requirements	Yes
Negotiate site agreements in collaboration with Sponsor	Yes
Attend and present at investigator/coordinator meeting	Yes
Conduct on-site qualifying/initiation visits	Yes
Develop monitoring plan in collaboration with OUS team	Yes

HCRI's Roles & Responsibilities	
Conduct on-site interim monitoring visits	Yes
Provide ongoing site management and site monitoring services	Yes
Distribute serious adverse event reports to the sites for submission to their IRB	Yes
Administer payments of investigator grants	Yes
Participate in project team meetings	Yes
Participate in teleconferences	Yes
Conduct on-site close-out visits	Yes
ECG CORE LAB	
Develop ECG MOP, ECG labels	Yes
Evaluate study ECGs	Yes
EQOL SERVICES	**N/A**
OUTSOURCED ACTIVITIES	
OUS Site Management & Monitoring (specific tasks for OUS vendor TBD)	No
Angiographic Core Laboratory (via subcontract)	Yes

Estimated Budget:

Trial Design & Development	
Protocol Development	$6,210
CRF Design	$18,430
Develop DMC Charter	$5,330
Subtotal	***$29,970***
Medical Management	***$26,033***
Medical Monitoring	***$66,025***
Safety Management	
Review & Processing of SAE CRFs	$99,558
Safety Reconciliation	$43,882
Cumulative Safety Reports	$34,422
Weekly Safety Reports	$18,645
Subtotal	***$196,506***
Project Management	
Project Oversight	$291,717
Internal/External Conferencing	$220,035
Investigator Meeting	$0
Subtotal	***$511,752***
Data Management	
Data Management Plan	$7,165
CRF Completion Guidelines	$6,940
Database Development	$98,937
Randomization Programming	$15,733
Event & Safety Database Programming	$12,800
Database Maintenance	$31,335
EDC Database Administration	$10,952
Dictionary Coding	$23,180
Data Processing Status Reports	$41,840
Data Cleaning	$474,045
Data Maintenance & Administration	$12,800
Subtotal	***$735,728***

Electronic Data Capture	
Site Assessments & Support Documentation	$11,250
Training	$36,300
Hosting	$85,550
Help Desk	$81,000
Licensing Fee	$49,325
Portal Set Up	$10,000
Submission Closeout	$15,000
User Management Utility	$4,500
Subtotal	***$292,925***
Statistical Analysis & Reporting	
Statistical Analysis Plan	$23,260
Primary Endpoint Report	$109,410
Statistical Report	$44,220
Annual Safety	$30,725
Subtotal	***$207,615***
DMC Services	
DMC Reports	$83,760
Estimated DMC Participant Costs	$16,000
Subtotal	***$99,760***
CEC Services	
Event Review & Processing	$113,277
Estimated CEC Participant Costs	$45,850
Subtotal	***$159,127***
Clinical Site Management Services (US Only)	
Site Management Services	$280,281
Project Administration	$23,862
Develop & Negotiation Site Contract/Budget	$10,440
Regulatory Document Collection	$28,240
Site Selection	$10,000
CRA Management	$18,303
Administration of Investigator Payments	$10,669
Subtotal	***$381,795***
Clinical Site Monitoring Services (US Only)	
Qualification/Initiation Visits	$47,840
Interim Visits	$278,720
Closeout Visits	$45,760

Ongoing Clinical Site Monitoring Services	$231,772
Subtotal	***$604,092***
ECG Core Laboratory Services	
ECG Start Up Costs	$4,758
ECG Read Costs	$96,110
Subtotal	***$100,868***
CSA Discount*	-$12,500
Total Non Pass Through HCRI Estimated Costs	**$3,399,696**
Total Non Pass Through OUS Vendor Estimated Costs**	**TBD**
PASS THROUGH COSTS	
Pass Through Costs (HCRI)	
Clinical Site Payments** ***(16 US Clinical Sites)***	
Clinical Site Start Up Payments	$80,000
IRB Initial Payments	$40,000
IRB Amendment Payments	$24,000
IRB Annual Payments	$36,000
Clinical Site Closeout Payments	$4,000
Subtotal	***$184,000***
Estimated Pass Through for Teleconferences	***$2,760***
Estimated Travel Costs	***$138,000***
Estimated Travel Costs Investigator Meeting	***TBD***
Total Pass Through HCRI Estimated Costs	**$324,760**
Pass Through Costs (OUS Vendor)	
Clinical Site Payments** ***(34 OUS Sites)***	
Site Start Up Payment	TBD
EC Initial Payment (Local)	TBD
EC Initial Payment (Lead)	TBD
EC Amendment Payments (Local)	TBD

EC Amendment Payments (Lead)	TBD
Clinical Site Close Out Payments	TBD
Subtotal	***TBD***
Other Estimated OUS Vendor Pass Through Costs	
Translations	TBD
Travel	TBD
Phone	TBD
Courier	TBD
Inflation/Stability	TBD
Subtotal	***TBD***
Total Pass Through OUS Vendor Estimated Costs**	**TBD**
Clinical Site Patient Payments (US & OUS)**	***$3,270,000***
Angio Core Lab Services	
Baseline Angio Analysis	TBD
Follow Up Angio Analysis	TBD
Data Entry	TBD
Subtotal	***TBD***
Grand Total	***$6,994,456 (plus costs TBD as outlined above)***

Source Budget: InspireMD – MGC10 MGuard Study Budget v9.0

* A $12,500 Credit on the Trial Design work has been given to InspireMD for paying the invoice HCRI sent on 12/20/2010 for Trial Design work.

** It is not anticipated that HCRI will subcontract with the OUS Vendor. If, ultimately, HCRI does contract with the OUS Vendor, all OUS Vendor costs will be billed from HCRI to InspireMD as a pass-through expense. It is the understanding of the parties that amounts due to the OUS Vendor will be invoiced to HCRI in the Euro. All OUS Vendor costs will be billed as a pass-through expense, reflecting the actual amount HCRI paid to the OUS Vendor in US Dollars at the time of payment.

*** Investigator Grants/Per-Patient Costs (for all patients) and IRB costs (for all US sites only) are included as shown above. Site payments for US and OUS sites will be billed according to the payment schedule, and shall be billed without markup.

**** Costs are based on 2010 labor rates. HCRI reserves the right to review and renegotiate labor rates with InspireMD on an annual basis, beginning one year from the date of this Agreement.

***** The budget contained herein does not include any potential fees HCRI may incur for administering site and/or patient payments to OUS sites. It is not anticipated that this service will be required, however, if requested by InspireMD, HCRI will assess potential wire fees at that time and a Contract Change Order will be issued.

Estimated Site Costs

Clinical Site Payments – US Only

Category	Unit Cost	Units	Cost
Site Start-Up Payments	$5,000/Site	16 Sites	$80,000
IRB Initial Payments	$2,500/Site	16 Sites	$40,000
IRB Protocol Amendments Payments	$500/Amendment/Site	3 Amendments, 16 Sites	$24,000
IRB Annual Renewal Payments	$750/Year/Site	3 Years, 16 Sites	$36,000
Site Study Close Out Payments	$250/Site	16 Sites	$4,000
Total Cost (per budget)			**$184,000**

Patient Payments – US and OUS

Region	Patients	Rate	Cost
US and OUS	654	$5000/patient	$3,270,000
Total Cost (per budget)			**$3,270,000**

Budget Companion

Study Start-Up

- **Protocol Review**

The study protocol is reviewed by many operating departments at HCRI, as well as clinical experts from the therapeutic area being studied. This will assist Project Team personnel in understanding the important scientific elements of the study. The review process will help to confirm not only the completeness of the scientific and clinical justifications, but also the clearness of detail for site compliance and conformity with both US and outside of the US regulatory guidelines.

Medical Management

Medical Management will be performed by physicians at HCRI. Their responsibilities will include protocol and case report form review, oversight for Clinical Event Committee (CEC) and Data Monitoring Committee (DMC) services, consultation to InspireMD and the HCRI Team for trial strategy issues, provision of overall medical support to HCRI Project Teams, and clinical review of report deliverables generated by HCRI. In addition, these physicians will be available as members of the Project Team for additional medical support, to answer study related clinical questions, and to provide medical review of SAE Regulatory Reports.

Safety Management

- **SAE Review & Processing with Narratives**

HCRI uses an Empirica™Trace database to track incoming SAEs which are received from sites through an e-mail notification system from the EDC database. InspireMD will also receive a notification of the SAE once it is received at HCRI. The SAE is entered into the Empirica™Trace database and MedDRA coded at the time of entry. We may contact the sites to gather sufficient information to generate a clear narrative of the event. If applicable, a Safety Regulatory Reporting document (MedWatch, CIOMS) may be generated for the SAE. All Safety Regulatory Reports will be sent to InspireMD, who will be responsible for submission to the appropriate regulatory authorities.

A coding review of adverse events will be performed on a periodic basis and prior to any report deliverable. This review will ensure that the appropriate medical concept is assigned through the standardized coding dictionary to every adverse event and that all events are coded in a consistent manner.

- **SAE Reconciliation**

The SAEs entered in Empirica™Trace will be reconciled with the SAEs in the EDC database based on information obtained on the eCRF. A Reconciliation Plan will be created which details all data elements to be reconciled and a timeline for review. This Reconciliation Plan will be reviewed with InspireMD prior to inclusion into the Data Management Plan. According to the timeline outlined in the Reconciliation Plan, periodic listings of all SAEs will be generated from Empirica™Trace and matched/reconciled against the EDC database. Queries will be generated for any data elements pertaining to an SAE that are inaccurate or not consistent between the two databases.

- **Weekly Safety Reports & Monthly Cumulative Reports**

Weekly Safety Reports provide an update for any UADE's and Deaths received in the previous week, with password-protect Word narrative attachments for new and follow up cases. Monthly Cumulative Reports list all SAEs processed within a pre-determined reporting frequency (i.e., monthly). The Weekly Safety Reports are provided manually while the Monthly Cumulative Reports are pre-programmed. Examples of such reports can be provided upon request.

Medical Monitoring

The Medical Monitor (MM) will be an interventional cardiologist- boarded and active in this area of clinical research. Prior to assuming duties, the MM will first complete all document training on applicable HCRI SOPs with regard to trial medical monitoring, good clinical practice, safety reporting, clinical trial management as well as training on this study protocol and the investigator brochure and protocol referenced literature and source documents.

The Medical Monitor will provide the following essential services for this study during normal business hours (weekdays) unless contacted by the Sponsor or the clinical site personnel for after hour emergencies.

The MM will ensure compliance with study protocol, regulatory requirements, and the integrity of data and safety of Trial subjects and will determine causality assessments of SAE events and determine their relationship and clinical significance to the Trial using medical judgment. The MM will also perform review of case report forms for events, narrative, concomitant medication, medical history to identify trend, discrepancy and will consult with site Principal Investigators to clarify inclusion/exclusion criteria for potential Trial subjects and verify eligibility prior to site access to subject randomization system as applicable. This will also include consulting with site Principal Investigator and Site Coordinator(s) in cases of premature subject discontinuation.

The MM will be available to the trial DMC and the CEC on an as needed basis regarding any background information with respect to any significant safety or compliance issues. The MM will also perform laboratory data review of study subject and determine clinical significance in consultation with Sponsor and Investigator based on information in Investigator's Brochure (IB) and scientific literature.

The MM will review any Trial protocol violations/deviations and initiate remedial action and site training to ensure corrective action is applied and the accuracy of the clinical trial data is intact. The MM will work with the Medical Director, Clinical Safety and the assigned Clinical Safety Associate of HCRI assigned to the Trial to monitor all Serious Adverse Events (SAEs) until resolution.

The MM also may be called upon to participate in meetings/teleconferences as required with the Sponsor, Study Team members and/or regulatory agencies as deemed appropriate.

Project Management

- **Project Oversight**

A Project Manager (PM) will lead the HCRI team in completing HCRI's Scope of Work for this project. The PM will facilitate communication among all team members and serve as InspireMD's point of contact for all study-related activities performed by HCRI. In addition, the PM will manage HCRI personnel's adherence to the study timelines, budgets and deliverables and provide review of study deliverables, including the CRFs, CRF completion guidelines, and reports. HCRI's Project Management team will include Project Assistants who will provide services such as meeting minutes, meeting scheduling, and other study administrative needs.

Additionally, it is anticipated that HCRI's PM will oversee the activities of the OUS Site Management and Monitoring vendor, but it is understood that InspireMD maintains responsibility for their performance unless the OUS vendor contracts directly with HCRI.

- **Internal/External Conferencing**

HCRI's Project Team will meet periodically to review all current matters relating to the study. The team members for this study will include the Project Manager, Project Assistant, Lead CRA, HCRI Physician, Data Manager, Clinical Reviewer, Safety Officer, Biostatistician, and Programmer, and EDC representative. In addition, a weekly conference call with InspireMD will be coordinated by the HCRI Project Manager and will include a review of study timelines and milestones as well as any other issues which may arise during the course of the study.

- **Investigators Meeting**

Investigators Meeting costs have been removed from the budget and Agreement pending further discussion between HCRI and InspireMD related to logistics and responsibilities.

Data Management Electronic Data Capture

This Agreement and budget is based on using HCRI's EDC resources and the InForm EDC system. In the event that HCRI's EDC services are not used, costs for all resources are subject to modification and a Contract Change Order will be issued.

- **Data Management and EDC**

Data management will be performed according to ICH-GCP and other applicable guidelines. HCRI will evaluate the trial in the design phase in order to create an efficient data management process specific to the study requirements, and in conjunction with EDC activities, that tracks toward delivering a clean, locked database within the required timelines. Every major element of the data management process is closely monitored by a lead Data Manager (DM) in accordance with HCRI's standard operating procedures (SOPs).

The DM will create eCRF Specifications and Edit Check Specifications in conjunction with review by the Project Team. To ensure delivery of a database that reflects the specifications and meets the quality expectations of HCRI, the DM will coordinate the database testing process. Once the trial goes live, the DM will review the eCRF data, including automated and manual queries, and raise manual queries as necessary. A 10% manual query rate is assumed based on HCRI experience with similar trials. A higher query rate will incur additional cost. The DM will address the status of queries and follow up with the sites to close automated and manual queries. The DM will lock the eCRF forms in accordance with the scope and definition of the project. The DM will produce standard enrollment and eCRF status reports throughout the trial and provide them to study management as defined in the Data Management Plan. Custom reports are available at additional cost to InspireMD.

The DM will prepare a Data Management Plan (DMP) that defines and documents the data management activities being performed. The DMP covers the scope of DM activities for the trial and includes a description of the data collection process, the workflow, documentation on the logic and processes for data review and validation, critical timelines and milestones, types of and timing of management reports, description and timing of data transfers, and documentation of external data reconciliation, as applicable. Early development and approval of the DMP is intended to enhance communication between all parties concerned, thereby leading to more efficient and accurate data collection. This plan will be reviewed and updated during the course of the project.

The DM will compile eCRF Completion Guidelines (CCGs) to instruct sites on accurate completion of the eCRFs. The CCGs will be reviewed and finalized with input from InspireMD and may be updated during the course of the project. Two drafts and one final version of the CCGs are assumed for this Agreement and budget. Additional drafts will incur additional cost.

- **eCRF Design**

HCRI will design eCRFs that capture the information needed to describe the eligible study population, patient characteristics, procedural details, safety and efficacy information of the investigational product, and of the study endpoints to be analyzed. It is assumed that HCRI standard eCRFs will be utilized. Changes to or requirements beyond the standard eCRFs may result in additional programming time and/or cost. eCRF specifications and versions will be developed collaboratively with InspireMD. Two iterations of drafts and one final draft with approval on the eCRF content and specifications are assumed for the purpose of providing this cost estimate. Additional changes may impact both cost and timelines for eCRF implementation.

- **Study Start-up and Database Build**

Once specifications are approved, the eCRFs will be programmed and a database established. HCRI will outline edit check specifications for consistency and accuracy of the data as it is being entered to the EDC system. These specifications will be reviewed internally by the database design team and presented to InspireMD for input and review. Once approved, these specifications will be programmed and added to the EDC database.

HCRI will create a formalized test plan for InspireMD's approval prior to database testing. Based on that plan, HCRI will develop test scripts and test data which will be executed internally to resolve any issues. InspireMD is invited to view and test the database during this timeframe. Once testing is complete and issues have been resolved, a Test Summary document will be prepared for review. After the final phase of trial verification occurs, HCRI will review and approve the documented process. The Project Team and InspireMD are required to approve the release of the study to the production environment.

- **Site Assessments and Support Documentation**

HCRI will electronically assess each site to ensure internet access and compatibility. HCRI will also collect user information and establish the site and user database for the trial. System configuration settings will be reviewed by the Project Team and InspireMD before incorporation into the system. All documentation is kept in a secure electronic library with version control.

- **Training**

InForm training will be provided using PhaseForward's InStruct Online solution. This internet based training is an easy to use e-learning system that allows users to learn in a self-paced training environment and provides worldwide documented course certification and re-certification. Upon course completion and a formal testing process, users will receive a Certificate of Completion in electronic PDF format and each user receives access to the course materials for one (1) year.

- **Hosting**

Hosting charges are based on the number of users and the number of patients in the study. Hosting is an ongoing monthly server charge, beginning at the "Go-Live" date, or the date the study is first made available for data entry. Hosting is terminated on the date the final study report is accepted by InspireMD at which point the server is decommissioned. If the study runs longer than projected, the monthly server charge is continued until the server can be decommissioned.

- **Data points/Licensing**

The licensing charge is a one-time fee based on the total number of expected forms/data points. If additional forms are programmed per sponsor request and the number of data points increases, the licensing fee may increase. This fee is reflective of server space being sectored and dedicated for this trial and is incurred in full at the time the trial goes live. Due to server and data integrity issues, the sectored database is "fixed"; this fee may not be reduced, and may be increased if the volume of data points increases from that shown in the Parameter Table in this Agreement.

- **Help Desk**

The technical Help Desk for EDC trials is billed monthly based on the number of sites. Help Desk is available in multiple languages and has been priced for 24 hours per day, 7 days per week. The Help Desk charge has been calculated from the "Go-Live" month until the trial is locked. An extended requirement for Help Desk services will incur additional costs.

- **EDC Database Administration/Maintenance**

EDC administration covers the required time to support the EDC system throughout the trial on teleconference and responding to questions from InspireMD and users. HCRI also monitors Help Desk and server issues, escalating or researching problems that may occur.

Changes to the database after "Go-Live" may result in a contract change order for out-of-scope requests. Changes that are made to forms or edit checks as a result of a protocol amendment or per client request will incur additional charges.

- **Study Portal**

The study portal is a central repository for site users to access the most recent versions of the protocol, CRF completion guidelines, and contact information. In addition, memos, newsletters, and FAQs can be posted on the portal for ease of access by all study users.

- **Submission Closeout**

Once the final study report has been issued, and the trial is ready to be archived, site-specific study data will be provided to each site and a complete set of data will be created for InspireMD. This data will be provided as a PDF (or other universally acceptable format) for easy navigation and to meet the applicable regulatory guidelines.

Statistical Analysis & Reporting

- **Statistical Analysis Plan**

The Statistical Analysis Plan (SAP) is a comprehensive and detailed description of the statistical methods and presentation of data analyses proposed for a clinical trial. The SAP is finalized prior to database locking and treatment code unblinding, in order to avoid post hoc decisions that may affect the interpretation of the statistical analysis. The SAP includes templates of tables, listings, and figures to be presented in the statistical report as well as definitions of all the populations to be analyzed (e.g., intention-to-treat, as-randomized, per-protocol). A unique SAP is designed for every study at HCRI.

- **Statistical Reports**

Statistical reports will be prepared based on the approved SAP. The statistical report includes tables, listings and graphs, as referenced in the study parameters above, generated using SAS and output using the ODS feature in SAS. A brief description of the study, statistical methods used in the analysis, results of the study and conclusions are also included. The report will also contain the event narratives, safety information, and a medical conclusion.

The tables and graphs are validated using double programming and 100% QC of all the statistics displayed. The listings are validated by checking 10% of the data displayed in the listings. The statistical report undergoes internal review at HCRI prior to being released.

HCRI has budgeted for 1 interim report, 1 primary endpoint report at 12 Months, and 1 annual report.

Clinical Events Committee (CEC) Services

HCRI has established a standing Clinical Events Committee under the guidance of the Executive Director of Clinical Investigations, Donald Cutlip, MD. The CEC will be responsible for adjudicating complications reported during the study that are related to the study endpoints.

This committee is comprised of 3-5 physicians with experience in clinical trial event adjudication, including at least one physician with expertise in each area of the study, who are not participants in the study and who meet regularly throughout the study to adjudicate events in an ongoing fashion. CEC members are chosen based on their clinical expertise and have no association with any trial for which they adjudicate events. The CEC is blinded to treatment assignment during all deliberations. Three voting members comprise a quorum.

The CEC drafts and agrees upon its working charter for each study prior to performing any work. This includes explicit rules outlining the minimum amount of data required, and the algorithm followed in order to classify a clinical event. HCRI will prepare the CEC Manual of Operations (MOP) based on this information and the CEC MOP will serve as the guideline for adjudication for the specific trial under review.

Clinical events related to the primary and secondary endpoints are identified through the use of pre-specified edit checks which identify potential endpoint related events. After review of the identified events by HCRI, support documentation for identified events is obtained from the site, if necessary, and a summary is written to describe the significant details of the event. These summaries, with appropriate support documentation, are presented to the physician members of the CEC. The results of the adjudications are entered into the Complications database as well as on an Adjudication eCRF within the Inform database after the CEC meeting. The Complications database is specifically created within the overall study database and is used in the preparation of DMC reports, as well as in all analyses of endpoint results.

CEC meetings are held approximately 3 times per month at HCRI's offices in Boston, MA. As documentation of the CEC meeting and each event under review, HCRI provides to InspireMD relevant supporting documentation and/or meeting minutes. The format of the information will vary depending on whether or not HCRI is involved with event narration.

Data Monitoring Committee (DMC) Services & Reporting

HCRI will manage Data Monitoring Committee (DMC) services for this study. A DMC charter will be generated by HCRI, for approval by the DMC. DMC members will be identified (either by InspireMD or InspireMD and HCRI), and HCRI will negotiate and execute confidentiality and consulting agreements with the members.

The PM will provide oversight for all DMC-related activities including:

- Holding meetings with the HCRI Project Team as well as with relevant Sponsor representatives prior to initiating contact with the DMC.
- Assuring that all members who accept the DMC invite are vetted through the HCRI Conflict of Interest process.
- Inviting potential DMC Members to participate on the DMC.
- Holding an initial kick-off meeting/teleconference with DMC Members to review the DMC Charter.
- Scheduling and facilitating the DMC Meetings/Teleconferences that occur at a mutually acceptable time for the DMC Members and the InspireMD.
- Distributing DMC Reports to the DMC Members for review and distributing feedback to InspireMD.
- Addressing any post-DMC Meeting/Teleconference questions or correspondence with regard to questions on the DMC Report or data integrity.

Prior to initiating contact with the DMC, the PM will schedule a teleconference with the relevant Sponsor representatives in order to discuss the process utilized by HCRI for DMC Management. Topics should include:

- Reviewing the overall HCRI DMC process.
- Describing the DMC Charter generation and review process.
- Identifying any potential concerns in advance of the first DMC meeting.
- Reviewing the process of inviting potential DMC Members.
- Participating in Open and Closed Session of DMC Meetings/Teleconferences.

- Recording DMC Meeting/Teleconference minutes.
- Ensuring that the DMC Meeting/Teleconference minutes are distributed and communication occurs between the DMC and InspireMD per the DMC Charter.
- Distributing the DMC Report to the DMC Members within the timeframe specified in the DMC Charter.

- **DMC Charter**

A study-specific DMC Charter will be created to guide the DMC. A Medical Writer drafts the DMC Charter upon reviewing the protocol and receiving specific guidance from InspireMD with respect to such issues as membership and number of meetings. Following internal review by HCRI team members, the draft is reviewed by InspireMD before being sent to the DMC via the Chair so that the DMC can review and provide feedback.

- **DMC Reports**

The DMC reports are usually generated from live data, which has not completed the "cleaning" process **.** HCRI will provide a dataset to a statistician who is not a member of the Project Team for analysis. This independent statistician will generate the unblinded tables and listings. The DMC report will undergo independent medical review by an HCRI physician and statistical review by an independent statistician before being distributed to the DMC. The HCRI Project Team and InspireMD will remain blinded to the interim analysis results.

This Agreement budgets for 3 DMC Reports and 4 DMC Meetings. Additional meetings or reports will result in additional costs.

Clinical Site Management and Monitoring (US ONLY)

HCRI will have managerial oversight of the study from study start-up through close-out as described below.

This study will be staffed with an experienced in-house team and with regionally-based contract monitors with an expertise in monitoring medical device studies. Each contract monitor assigned to the study will go through an interview process to ensure that they have the necessary background and experience to meet the needs of the study. InspireMD may also be involved in the interview process, if requested. All monitors assigned to the study will have extensive experience in training sites and conducting site visits in accordance with FDA Regulations and International Conference on Harmonization (ICH)guidelines.

- **Investigator Selection**

HCRI will collaborate with InspireMD to identify a list of potential Investigators with proven experience at successfully enrolling patients and providing quality data. As soon as InspireMD approves the first list of Clinical Sites and Investigators, HCRI will begin contacting those Clinical Sites to assess their interest and capabilities to conduct the study. HCRI will develop a site selection questionnaire that will focus on the following areas:

- Overall clinical trial set up
- Available patient population
- Enrollment potential including an ability to screen patients or receive referrals
- Current research staff including 24/7 screening and enrollment coverage
- Competing studies – both for the same patient population and for research staff's time
- Device storage requirements
- Key IRB timelines
- Budget requirements

Once the site selection questionnaire has been returned to HCRI, it will be reviewed in collaboration with InspireMD. After a final list of Clinical Sites has been agreed upon and approved by InspireMD, a Confidential Disclosure Agreement (CDA) will be forwarded to each Clinical Site for signatures so the study start-up process can begin.

- **Informed Consent**

HCRI can assist InspireMD as needed with drafting a template informed consent in English to be used by each Clinical Site for submission to its Institutional Review Board (IRB). The informed consent will meet the ICH Guidelines for Good Clinical Practice as published in the Federal Register May 9, 1997. HCRI will review each Clinical Site's informed consent template to ensure it meets regulatory standards prior to IRB submission.

- **Study Start-Up and Clinical Site Qualifications**

Per Sponsor request, a combination QSA/Initiation visit will be conducted if HCRI or InspireMD has previously qualified the Clinical Site for the same indication.

Clinical Sites selected will receive a complete regulatory document packet customized for the study to assist with IRB submissions. HCRI will collect and review all regulatory documents for accuracy, completeness, and regulatory compliance. Once each Clinical Site has all its regulatory documents in order, an Investigator Study Binder will be provided to each Clinical Site to store all study related documents as well as house instructional manuals and study tools.

Once a Clinical Site has been approved to commence enrollment, a combination Qualification/Initiation Visit will be conducted. This visit will ensure that the study staff understands all aspects of the study, including protocol and CRF review, review of regulatory requirements, specific study procedures, the informed consent process, and device accountability. This visit will be conducted once each site has received IRB approval and has executed a clinical study agreement with InspireMD, and once all study supplies, including study device, have been received by the site. An Initiation Visit report will be submitted to InspireMD.

- **Clinical Site Study Aids**

HCRI will work with InspireMD to develop any study aids for the Clinical sites. These include such aids as inclusion and exclusion cards, source document worksheets, and protocol flip cards.

- **Clinical Site and Study Metrics**

Study metrics will be provided to InspireMD on an agreed upon schedule. The metrics will include an overview of Clinical Site status, enrollment by site, a monitoring visit schedule and completed visits. HCRI will work with InspireMD at the start of the study to determine the preferred metrics and timeframes for providing these metrics.

- **Interim Monitoring Visits**

Interim monitoring visits will be conducted at each Clinical Site at a regular frequency according to the study needs during enrollment and follow-up. Each visit can last anywhere from 6-8 hours and will be dependent upon the Clinical Site's patient enrollment rates and the complexity of the source document verification. Between monitoring visits, the Clinical Research Associates (CRAs) will contact Clinical Sites to assess enrollment activity, answer study related questions, resolve queries and assist with any other issues regarding study conduct. This contact will occur every one to two weeks. If additional onsite interim monitoring visits are needed, InspireMD will be consulted for approval. Interim Site Visit Reports will be submitted to InspireMD following each visit.

At the Interim Monitoring Visits the CRA will:

- Assess enrollment and continuing protocol adherence;
- Review all relevant source documents, in accordance with the Monitoring Plan;
- Report any previously unreported SAEs to HCRI and InspireMD;
- Investigate and resolve any outstanding queries;
- Ensure that the investigational product is accounted for and that records are accurate;
- Conduct a continuing review of the Investigator study file for regulatory adherence and to ensure that GCP/ICH guidelines are being followed, and
- Perform 100% source documentation of the data entered, unless otherwise specified by InspireMD.

- **Close-Out Monitoring Visits**

A Closeout Monitoring Visit will be performed at each Clinical Site at the end of the study to ensure regulatory compliance with regard to record retention, proper disposition and accountability of the study device, and, most importantly, that the site is audit-ready. A Close-Out Visit report will be submitted to InspireMD.

- **Clinical Site Contracts & Clinical Site Payments**

HCRI will negotiate Clinical Site contracts and budgets on behalf of InspireMD. HCRI will also administer grant payments to the Clinical Sites to include IRB fees, startup fees, and per-patient stipends for US Clinical Sites and at the request of InspireMD may do payments for the OUS vendor, subject to an agreed upon CCO. Site budget estimates have been included in this Agreement.

- **Clinical Trial Management System (CTMS)**

HCRI has an in-house Clinical Trial Management System to manage and monitor Clinical Site information and status, Clinical Site documentation, subject screening and enrollment and Clinical Site monitoring. Internal HCRI employees will utilize the system for tracking study related activities. Contracted Clinical Site monitors will utilize the system to document all Clinical Site visits and submit site visit reports.

- **OUS Site Management and Monitoring**

InspireMD will subcontract site management and monitoring services for OUS Clinical Sites to a yet-to-be-determined OUS vendor.

ECG Core Laboratory Services

Incoming 12 lead ECGs will be evaluated for demographic consistency and recording quality. ECG tracings will be manually evaluated by board certified Cardiologists/Electrophysiologist. ECG tracings will be read and interpreted with the comprehensive evaluation of rhythm, conduction intervals, and morphology. ECGs will be evaluated at pre-procedure, hospital discharge, and events.

Budget Assumptions & Notes

Estimates Contained Herein :

The Estimated Budget for the Agreement is based upon the Project Parameters and Task Matrix detailed above. Should any of these Parameters or Responsibilities change, HCRI will prepare a Contract Change Order.

Timelines

InspireMD acknowledges and agrees that HCRI's ability to meet agreed upon timelines will be critically dependent upon the actions, approvals, directions and/or information of or to be provided by InspireMD or its agents that directly or indirectly impact HCRI Services. If HCRI considers any such actions, approvals, directions and/or information or omissions of same problematic and potentially having an adverse effect on its ability to provide Services and meet established timelines, HCRI will promptly advise InspireMD of such concerns. InspireMD agrees to provide any reasonable assistance and take any related actions to address the concerns presented by HCRI with regard to InspireMD's requests. In the event that HCRI does not receive adequate assistance to address the concerns presented as required to meet established timelines, the timelines will be revised by InspireMD, if necessary, subject to mutual agreement by HCRI. In the event that the project duration or other factors vary from those estimated for this Agreement, HCRI may renegotiate the timing and amounts of the payment schedule to reflect actual conduct of the project.

Documents and Deliverables :

All study documents and deliverables shall be delivered by HCRI in accordance with timelines established. The determination of deliverable timelines shall reflect the reporting requirements of InspireMD together with the operational requirements and capabilities of HCRI. All study deliverables will require two (2) drafts before finalization. InspireMD will submit one (1) set of consolidated comments for the review of all draft documents and deliverables.

InspireMD recognizes that any delay by InspireMD or a 3rd party relied on by InspireMD for the purpose of this Study may result in delays in HCRI deliverables and/or the overall timeline which may result in a change in scope.

Costs are based on 2010 labor rates. HCRI reserves the right to review and renegotiate labor rates with InspireMD on an annual basis, beginning one year from the date of the Agreement.

At the request of InspireMD, estimates of Investigator Grants and IRB costs have been included, beginning in this Agreement. Because HCRI has not had the opportunity to specifically contact sites with a study protocol and obtain estimates, these amounts are subject to change.

Estimated travel costs for attending and participating in the investigators meeting are included. Actual travel costs will be invoiced to InspireMD on a time and materials basis. Meeting expenses will be invoiced to InspireMD as a pass-through expense.

Out of scope meetings with InspireMD are **not** included in the budget and will incur additional charges. For all out of scope meetings, HCRI will invoice InspireMD on a time and materials basis for actual time associated with meeting attendance. Travel expenses (flight, lodging, food) associated with this Agreement, if any, will be invoiced as a pass-through expense.

Teleconference costs for DMC Meetings and other team teleconferences that are hosted by HCRI using HCRI's dial-in number will be invoiced to InspireMD as a pass-through cost.

Estimated costs for ECG Core Laboratory services have been provided. InspireMD will be invoiced for a $4,758 startup fee and for actual ECG Core Laboratory costs based on the actual number of readings conducted at a rate of $70 per ECG.

Costs associated with the preparation, processing and narrative generation of Serious Adverse Events (SAE) estimated in this budget is a variable cost based on the following assumptions:

- Maximum of 2 manual queries per SAE
- Maximum of 2 updates to the initial SAE review
- Review of 5 pages of source documents per SAE

Increases to any of the parameters outlined above will be subject to out-of-scope fees and revisions to the SAE review/processing cost(s).

Estimates for DMC participant costs have been estimated at a rate of $4,000 per meeting and will be invoiced to InspireMD separately based upon the actual number of meetings held.

Costs associated with the preparation, processing and adjudication of clinical endpoints estimated in this budget is a variable cost based on the following assumptions:

- Receipt of a completed dossier as outlined by the minimum data requirements sheet (which includes CRF data and source documentation).
- Maximum of 2 manual queries per event
- Review of an average of 5 pages of source documents per event identified for adjudication

Increases to any of the parameters outline above will be subject to out-of-scope fees and revision to the CEC services costs.

CEC physician costs will be invoiced at a rate of $350 per actual event adjudicated by the CEC.

Costs for developing the CEC MOP include up to two (2) drafts for finalization. Additional drafts are subject to out-of-scope fees.

Monitoring travel costs have been estimated at a rate of $1,200 per trip.

HCRI will invoice InspireMD for any printing, shipping, or binding required during the course of the project as a pass-through expense.

Distribution of MedDRA terminology, or analysis based on MedDRA terminology, to the sponsor or the sponsor's use of MedDRA will require the sponsor to have and maintain a valid MedDRA license. DMC reports will be exempt from this requirement if the DMC is managed by HCRI. Information can be found regarding licensing on the MSSO web page, www.msso.org.

InspireMD will be responsible for obtaining a license to the WHO DD, WHO DDE or WHO DDE+WHO HD. HCRI will not offer any compensation for such license. It is the responsibility of both HCRI and InspireMD to validate via the UMC that the other party has the proper license. The validation request application is to be found at the following URL: http://www.umc-products.com/validation.

InspireMD is responsible for notifying the FDA of its intent to use electronic signatures in compliance with 21 CFR, Part 11.

EXHIBIT B

Schedule of Fees

The fees identified below will be paid by Sponsor to HCRI for the services described in the Agreement.

Milestone	EDC Services	Trial Services	Site Management Services	Site Monitoring Services (US)	Site Monitoring Services (OUS)	Site & Patient Payments	Monitor Travel	Total
Upon execution of CTSA	$27,844	$86,783	$22,351	$10,530	$0	$37,500	$2,400	$187,408
Upon 60 days after execution of CTSA	$27,844	$86,783	$22,351	$10,530	$0	$37,500	$2,400	$187,408
Upon Sponsor approval of eCRFs	$0	$18,430	$0	$0	$0	$0	$0	$18,430
Upon Establishing Date for Investigators' Meeting	$0	$0	$0	$0	$0	$0	$0	$0
Upon Submission of Regulatory Packet to 1st US Site	$0	$0	$14,900	$14,994	$0	$15,000	$4,800	$49,694
Upon 50% of US Sites Initiated	$0	$0	$14,900	$14,994	$0	$15,000	$4,800	$49,694
Upon 100% of US Sites Initiated	$0	$0	$14,900	$14,994	$0	$15,000	$4,800	$49,694
Upon EDC Database Go-Live	$55,688	$173,565	$0	$0	$0	$0	$0	$229,253
Upon Delivery of the Statistical Analysis Plan	$0	$23,260	$0	$0	$0	$0	$0	$23,260
Report Milestones								
Upon database lock for Primary Endpoint (12M) report	$0	$54,705	$0	$0	$0	$0	$0	$54,705
Upon delivery of Primary Endpoint report	$0	$54,705	$0	$0	$0	$0	$0	$54,705
Upon delivery of Statistical (30D) report	$0	$44,220	$0	$0	$0	$0	$0	$44,220
Upon delivery of 1st DMC report	$0	$27,920	$0	$0	$0	$0	$0	$27,920
Upon delivery of 2nd DMC report	$0	$27,920	$0	$0	$0	$0	$0	$27,920
Upon delivery of 3rd DMC report	$0	$27,920	$0	$0	$0	$0	$0	$27,920
Upon delivery of Annual Safety report	$0	$30,725	$0	$0	$0	$0	$0	$30,725
Enrollment Milestones								
Upon enrollment of 1st patient	$12,108	$81,764	$19,493	$35,870	$0	$0	$7,920	$157,155
Upon enrollment of 50th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 100th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 150th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 200th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 250th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 300th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 350th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148

Upon enrollment of 400th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 450th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 500th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 550th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of 600th patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon enrollment of last patient	$12,103	$81,762	$19,493	$35,870	$0	$0	$7,920	$157,148
Upon completion of last patient follow up	$12,103	$81,762	$19,491	$35,869	$0	$0	$7,920	$157,145
Quarterly Milestones (Calendar Quarters)								
Upon Q1 after first patient enrolled	$0	$0	$0	$0	$0	$553,000	$0	$553,000
Upon Q2 after first patient enrolled	$0	$0	$0	$0	$0	$553,000	$0	$553,000
Upon Q3 after first patient enrolled	$0	$0	$0	$0	$0	$553,000	$0	$553,000
Upon Q4 after first patient enrolled	$0	$0	$0	$0	$0	$335,000	$0	$335,000
Upon Q5 after first patient enrolled	$0	$0	$0	$0	$0	$335,000	$0	$335,000
Upon Q6 after first patient enrolled	$0	$0	$0	$0	$0	$335,000	$0	$335,000
Upon Q7 after first patient enrolled	$0	$0	$0	$0	$0	$335,000	$0	$335,000
Upon Q8 after first patient enrolled	$0	$0	$0	$0	$0	$335,000	$0	$335,000
To Be Billed as Incurred (Monthly/Quarterly)								
Medical Management (Quarterly - $2,893/quarter)	$0	$26,033	$0	$0	$0	$0	$0	$26,033
Medical Monitoring (Monthly - $2,063/month)	$0	$66,025	$0	$0	$0	$0	$0	$66,025
CEC Participant Costs (131 events @ $350/event)	$0	$45,850	$0	$0	$0	$0	$0	$45,850
DMC Participant Costs (4 meetings @ $4,000/mtg)	$0	$16,000	$0	$0	$0	$0	$0	$16,000
Teleconference Pass Through Charges	$0	$2,760	$0	$0	$0	$0	$0	$2,760
ECG Read Costs (1373 reads @ $70/read)	$0	$96,110	$0	$0	$0	$0	$0	$96,110
Travel Costs for Investigators' Meeting	$0	$0	$0	$0	$0	$0	$0	$0
Credit for CSA Trial Design	$0	-$12,500	$0	$0	$0	$0	$0	-$12,500
Total	**$292,925**	**$2,136,145**	**$381,795**	**$604,092**	**$0**	**$3,454,000**	**$138,000**	**$6,994,456**

Sponsor agrees to pay each invoice upon receipt of the invoice. Accounts not paid within forty-five (45) days of receipt of an invoice will be considered overdue.

In the event the Agreement is terminated prior to reaching a payment milestone, Sponsor agrees to pay HCRI for a pro-rated portion of the milestone on a time and materials basis for actual work performed and documented.

Note: The amounts presented above are for Clinical Trial Services provided by HCRI and for estimated CEC meeting and Core Laboratory costs. Sponsor will pay HCRI for CEC meeting and Core Laboratory fees based on the actual number of potential events brought to the CEC for adjudication and the actual number of ECGs read, respectively. Costs such as printing and shipping of CRFs and related materials, travel expenses, overnight shipping, and other expenses incurred in connection with the trial are not included and will be invoiced to Sponsor as a pass-through expense.

PAYMENT INSTRUCTIONS :

BY CHECK :

Checks should be payable to “Harvard Clinical Research Institute, Inc.”
All funds must be remitted in US Dollars

Tax ID #: 04-3521077

Contact: John Cunningham
John.Cunningham@hcri.harvard.edu
Phone: (617)307-5496

Regular Mail :

Harvard Clinical Research Institute, Inc.
P.O. Box 846057
Boston, MA 02284

Overnight Carriers :

Harvard Clinical Research Institute, Inc.
Lockbox Department MMF250
20 Cabot Road
Medford, MA 02155

BY WIRE TRANSFER :

Account Name:	Harvard Clinical Research Institute, Inc.
Account Number:	1105095700
Bank Name:	Citizens Bank 870 Westminster Providence, RI 02195
ABA Number:	011500120
Bank Telephone:	(800) 361-2472