# RESEARCH CONSULTING AGREEMENT

This Research Consulting Agreement ("**Agreement**") is entered into this __ day of _____ 2011 ("the Effective Date") by and between Duke University, a nonprofit educational and health care institution, with offices at 2400 Pratt Street Durham, North Carolina, 27705 ("**Duke**"), and Richard Steinman, ("**Consultant**"), an individual residing at 363 Park Avenue, Yonkers, New York 10703 (collectively, "the **Parties**").

**WHEREAS**, Duke was awarded a federal grant issued from the Agency for Health Research Quality **("AHRQ")**, to conduct a program of clinical research entitled, ***"Preventing Sudden Cardiac Death: Harnessing the Power of Decision Analysis, Bayesian Techniques, and Clinical Trials,"*** Grant No. R01HS018505 (the "**Project"**), which Project involves combining data from ten (10) sudden cardiac death (**"SCD"**) trial datasets in order to develop and inform a decision modeling framework and a Bayesian prediction model, which model will be applied to policy questions related to treatment of SCD;

**WHEREAS**, Consultant wishes to participate in the Project as a consultant, in which capacity Consultant shall assist Duke with obtaining a Limited Data Set of data from the Trustees of Columbia University's "CABG-PATCH" clinical trial and associated information, and providing Duke with advice relating to that data for purposes of the Project (the "**Services**");

**WHEREAS**, Consultant has the knowledge, the requisite skills, and experience to undertake such Services; and

**NOW, THEREFORE**, the Parties agree as follows:

1. **Scope of Work.** The Services shall be provided as set forth in the Scope of Work attached hereto as **Exhibit A**. Consultant agrees to use best efforts to perform the Services required under this Agreement. If Consultant is unable to continue the Services, this Agreement shall be terminated in accordance with Section 8. Consultant shall promptly notify Duke if Consultant becomes aware of any reason that he may be unable to complete the Services.

2. **Project Materials.** Duke shall enter into a mutually agree Data Use Agreement with Consultant's employer, the Trustees of Columbia University (**"Institution"**), providing access to data from the CABG-PATCH clinical trial and related information for purposes of the Project. Duke does not anticipate providing Consultant with direct access to that dataset. If Consultant does require access to data from the CABG-PATCH clinical trial it is expected that Consultant will obtain access from Institution.

3. **Conflict of Interest.** Consultant affirms that to the best of his/her knowledge, there exists no actual or potential conflict of interest between Consultant's family, business or financial interests and Services provided under this Agreement. Consultant represents that neither he, nor his spouse or dependent children, if applicable, have a financial stake in the design, conduct, outcome or reporting of research under this Project. Consultant

will not hire any employee of Duke or any employee of the United States government to perform any aspect of the Services. Consultant represents and warrants that he has obtained any necessary approvals from Institution**,** to provide the Consulting Services, and that the Services will create no conflict of interest with respect to his responsibilities to Institution or its affiliates. Consultant will promptly notify Duke if any such conflict or potential for conflict arises. Consultant shall not be required to conduct any Services hereunder that would in any way conflict with Consultant's continuing obligations to Institution.

**4.** **Compliance with Laws.** The Services will be conducted in accordance with, and the Consultant will comply with, all federal, state, and local laws and regulations applicable to the Services, including the federal "Certifications and Assurances" outlined in **Exhibit D**, as applicable.

**5.** **Payments.** In consideration of the Services to be performed under this Agreement and upon receipt of a detailed invoice, Duke shall pay Consultant in accordance with the budget and payment schedule (**"Budget and Payment Schedule"**) attached hereto as **Exhibit B**. Payments shall be made to the payee set forth in **Exhibit C**. This compensation includes all applicable taxes, necessary permits, licenses and insurance coverage.

**6.** **Independent Contractor.** Consultant's relationship to Duke and the AHRQ under this Agreement shall be that of an independent contractor and not that of an agent, joint venturer, or partner of Duke or the AHRQ.

**7.** **Effective Date and Term.** This Agreement shall become effective upon the date first set forth above and shall thereafter remain in full force and effect until July 31, 2011, the end of "Award Year 2," or termination of this Agreement as provided for in Section 8. Future Award Years and payments beyond Award Year 2 are subject to availability of funds from the AHRQ, satisfactory progress of the overall Project and amendment of this Agreement.

**8.** **Termination.** Either Party may terminate this Agreement immediately due to the breach or default of the other Party upon written notice to the other Party. Duke may terminate the Agreement upon thirty (30) days written notice, if it becomes for any reason, unable to perform or complete the Project. Duke may terminate the Agreement upon thirty (30) days written notice if AHRQ terminates or reduces funding for the Project, or if Consultant is unable to complete the Project and the Parties are unable to agree upon a successor. Duke shall be responsible for funding all work completed and expenses, if applicable, committed through the date of termination, and shall prorate financial support due based upon actual work performed and expenses committed pursuant to the budget. Sections 9, 10, 11, 12, 13, 14, 15 and 17 shall survive any termination of this Agreement.

**9.** **Data and Reporting.** Consultant will keep Duke informed of the progress of the Services and promptly report results of analyses to Duke as they are developed.

Consultant will provide a full and complete annual report to Duke not later than the end of each Award Year as delineated in Exhibit B. All data, analyses, and other relevant information generated as a result of the Services will be promptly and fully disclosed to Duke, and shall be freely usable by Duke for the purposes of the Project and for Duke's own research, educational and patient care purposes.

**10. Recordkeeping; Access.** Consultant will cooperate with Duke with respect to the creation and retention of written records of Consultant's Services. For a period of three (3) years following the completion of work performed hereunder, Consultant shall make available, upon written request by Duke or appropriate government agent, this Agreement and such books, documents and records as are necessary to certify the nature and extent of cost incurred by Duke.

**11. Inventions.** It is recognized and understood that certain existing inventions and technologies are the separate property of Consultant or Duke and are not affected by this Agreement, and neither Party shall have any claims to or rights in such separate inventions and technologies. Any new inventions, developments, or discoveries resulting from the Services (**"Inventions"**) shall be promptly disclosed in writing to Duke. Title to Inventions shall be based upon inventorship determined in accordance with United States patent law or by mutual agreement if the Invention is not patentable. Duke shall be free to use all Inventions for Duke's non-commercial, research, educational and patient care purposes. As the work conducted hereunder is funded by the U.S. Government, Inventions made hereunder are subject to certain government rights as set forth in 37 CFR 401.14. Subject to Duke's rights and the right of the U.S. Government, each Party shall be free to exploit its solely owned Inventions as it wishes. In the case of an Invention that is jointly owned between Institution and Duke, the Parties agree to enter into an Inter-Institutional Agreement providing for fair and equitable sharing of patent costs, income, and invention management responsibilities based on each Party's contribution to the Invention.

**12. Confidential Information.** "Confidential Information" means all information related to the Project provided to Consultant by Duke, the AHRQ or other participants in the Project, and all information generated by, or as a result of the Services. Specifically excepted from Confidential Information is all information that:

(a) was previously known to Consultant;

(b) is published or otherwise publicly disclosed except by breach of this Agreement either prior to or subsequent to Consultant's receipt of such information;

(c) is rightfully received by Consultant from a third party without an express obligation of confidence;

(d) is independently developed by personnel of either Party who are not working under this Agreement; or

(e) is disclosed pursuant to any judicial or government request, requirement or order, provided that the disclosing Party takes reasonable steps to provide the other Party with sufficient prior notice in order to allow the other Party to contest such request, requirement or order.

Consultant shall hold all Confidential Information in trust and confidence for Duke using the same care and discretion that Consultant uses with similar information which it considers confidential, but in no event less than a reasonable standard of care. Consultant will not use Confidential Information for any purpose other than for the Services in accordance with the terms of this Agreement. These obligations of confidentiality shall continue for the term of this Agreement and for three (3) years thereafter, except that all information constituting Protected Health Information shall be held in confidence without limitation of time.

**13. Publication.** Consultant acknowledges that he does not have an independent right to publish the results of the Services or the overall Project; however, Consultant shall be included as an author in publications prepared by Duke to the extent his contribution meets the requirements of authorship delineated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors.

**14. Indemnity and Insurance.** Consultant understands and agrees that neither Duke nor the AHRQ will provide any indemnification or insurance for Consultant's Services pursuant to this Agreement, and that it is Consultant's responsibility to carry appropriate liability insurance in an amount reasonably sufficient to protect against liability hereunder. Consultant shall provide proof of said insurance upon Duke's request.

**15. Use of a Party's Name.** Neither Party will, without the prior written consent of the other Party, use in advertising, publicity or otherwise, the name, trademark, logo, symbol or other image of the other Party or that Party's employee or agent, except that Duke may acknowledge Consultant's role in academic publications including the results of the Services.

**16. Debarment**. Consultant hereby certifies that he has not been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335a(a) and (b). In the event that during the term of this Agreement, Consultant (i) becomes debarred or (ii) receives notice of an action or threat of an action with respect to its debarment, Consultant shall notify Duke immediately. In the event that Duke receives notice that Consultant is debarred, or threatened with a debarment action as set forth in clause (ii) above, Duke shall have the right to terminate this Agreement immediately.

**17. Notice.** Any notice or other communication required or permitted under the Agreement shall be in writing and shall be deemed given as of the date it is received by the receiving Party. Notice shall be given to the Parties at the addresses listed below:

| | |
|---|---|
| As to Duke: | Duke Clinical Research Institute<br>Contracts Management<br>0311 Terrace Level<br>2400 Pratt Street<br>Durham, NC 27705 |
| As to Consultant:<br>– Home Address: | Richard Steinman<br>363 Park Avenue<br>Yonkers, New York 10703 |
| Consultant's Phone #: | _____ |
| Consultant's Fax #: | _____ |

**18. Modification and Amendment.** Any alteration, modification, or amendment to this Agreement must be in writing and signed by both Parties.

**19. Subcontracting and Assignment.** This Agreement is for professional services to be conducted by Consultant. Consultant shall not subcontract any of his rights or obligations hereunder. This Agreement may not be assigned by either Party without the prior written consent of the other.

**20. Governing Law.** The law of North Carolina shall govern this Agreement.

**WHEREFORE**, the Parties hereto place their hands and seals:

| **Consultant** | **Duke University** |
|---|---|
| **BY:** _____ | **BY:** _____ |
| Richard Steinman | Office of Research Administration |
| Date Executed:_____ | Date Executed:_____ |

## EXHIBIT A

## SCOPE OF WORK

For purposes of the Project, Duke will combine data and information from ten (10) sudden cardiac death (SCD) trial datasets. Consultant will facilitate Duke's obtaining access from Institution to a limited data set of data from the CABG-PATCH clinical trial, along with any necessary case report forms, data dictionaries, or other supplementary information. Consultant will also provide clinical expertise related to the limited data set and other information from the CABG-PATCH clinical trial.

## EXHIBIT B

## BUDGET and PAYMENT SCHEDULE

Payments, in accordance with the following schedule, will be made upon submission of an invoice by Consultant setting forth charges in accordance with the rates detailed below. The invoice must include Consultant's taxpayer identification number (Social Security or Employer ID Number). Payment Terms are Net 30 days.

| **Projected Payments Schedule** | | | |
|---|---|---|---|
| **Award Year** | **Payment Date** | **Payment Amount** | **Cumulative Amount** |
| **Award Year 2**<br>(08/01/2010 – 07/31/2011) | Payable upon Duke's receipt of CABG-PATCH dataset from Institution | $4,000 | $8,000 |
| | 07/31/2011 | $4,000 | |
| **Award Year 3***<br>(08/01/2011 – 07/31/2012) | 07/31/2012 | $4,000 | $12,000 |
| | | **TOTAL** | $12,000 |

**Payment contingent upon continual progress toward deliverables stated in attached Scope of Work.**

***Note: Future Award Years and payments beyond Award Year 2, are subject to availability of funds from the AHRQ, satisfactory progress of the overall Project and amendment of this Consulting Agreement.**

**EXHIBIT C**

# Payee Information

**Payee Name** – Entity to whom payment will be made
(maximum 35 characters - one line)

**Attention** – Person or Department to whom payments will be mailed
(maximum 35 characters – one line)

**Address**
(maximum 35 characters – one line)

**City** **State/Province** **Postal Code/Zip Code**

**Federal Tax ID#**

**SSN** (Required if Payee is an Individual)

# EXHIBIT D

## Certifications and Assurances (as applicable)

All references in this Exhibit D to "Subcontractor" shall be taken to mean Consultant.

1. Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex discrimination, Age Discrimination). Subcontractor certifies that it has filed with the DHHS Office for Civil Rights: an Assurance of Compliance with Title VI of the Civil Rights Act of 1964 (P.L. 88352, as amended), Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), Title IX of the Education Amendments of 1972 (P.L. 92-318, as amended), and the Age Discrimination Act of 1975 (P.L. 94-135).

2. Protection of Human Subjects. Pursuant to 45 CFR 46, Subpart A, Protection of Human Subjects, Section 46.107, the subcontractor agrees that any human research protocol conducted under this Agreement shall be reviewed and approved by Subcontractor's Institutional Review Board (IRB) before any human research subjects are included in the project. Subcontractor certifies that this IRB is in full compliance with all relevant federal regulations, and has an approved assurance on file with OHRP.

**a.** All individuals responsible for the conduct of any Human Subjects Research shall have completed an appropriate program of education in the protection of human subjects.

**b.** Research involving human subjects must comply with the "NIH Guidelines on the Inclusion of Women and Minorities in clinical research as Subjects in Clinical Research."

**c.** Research involving children must comply with the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects."

**d.** If research on the transplantation of human fetal tissue is conducted, Subcontractor certifies that they will make available for audit by the Secretary, DHHS, documents as required by section 498A(b)(2) and (c) of the PHS Act, 42 USC 289g(b)(2) and or ensure DHHS access to those records, if maintained by another entity.

**e.** If research using human embryonic stem cells is proposed, the Subcontractor certifies that they will be in compliance with the "Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry" (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html).

3. Vertebrate Animals. Pursuant to the Animal Welfare Act and the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the subcontractor agrees that any animal research protocol conducted under this Agreement shall be reviewed and approved by Subcontractor's Institutional Animal Care and Use Committee (IACUC) before any animal research is undertaken in the project. Subcontractor certifies that its IACUC is in full compliance with all relevant federal regulations and has an approved General Assurance on file with OLAW.

4. Research Involving Recombinant DNA Molecules, including Human Gene Transfer Research. Subcontractor agrees to comply with NIH Guidelines for Research Involving Recombinant DNA Molecules as amended www4.od.nih.gov/oba/rac/guidelines/guidelines.html), if performing any related research under this Agreement.

5. Debarment and Suspension. The subcontractor certifies to the best of its knowledge and belief, that it is not presently debarred, suspended, or proposed for debarment, or declared ineligible for the award of subcontracts, by any Federal Agency, in accordance with Office of Management and Budget (OMB) guidelines (53 FR19161-19211).

6. Certification of Non-Delinquency on Federal Debt. The subcontractor certifies that they are in compliance with the Non-Delinquency on Federal Debt criteria, in accordance with OMB Circular Number A-129.

7. Certification of Drug-Free Workplace. The subcontractor certifies that it has implemented appropriate policy in accordance with the Government-wide Requirements for a Drug Free Workplace, 45 CFR Part 82, and will comply with requirements to notify NIH in the event that an employee is convicted of violating a criminal drug statue..

8. Certification Regarding Lobbying. If the funds received exceed US$100,000, the Subcontractor certifies that, in accordance with 31 U.S.C. 1352, that it will not use Federal appropriated funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments.

9. Certification regarding Research Misconduct. The Study Site will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent research misconduct, and fulfill the responsibilities in dealing with and reporting possible research misconduct as set forth in 42 CFR Part 93, Public Health Service Policies on Research Misconduct. The Study Site certifies that it has established the required administrative policies, and will comply with those policies and the requirements of the regulations (see http://www.ori.dhhs.gov).

10. Financial Conflict of Interest. Study Site certifies that it will comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought", to ensure that there is no reasonable expectation that the design, conduct, or reporting of the Study will be biased by any conflicting financial interest of an investigator. Study Site certifies it has a written and enforced administrative process in accordance with that regulation to identify and manage, reduce or eliminate conflicting financial interest with respect to federally funded research projects in accordance with the requirements of 42 CFR Part 50, Subpart F.

11. Smoke Free Workplace / Children's Services. If applicable to this agreement, subcontractor agrees to comply with the requirements of P.L. 103-227, Part C of The Pro-Children Act of 1994.

12. Controlled Substances. If controlled substances are to be administered as part of a Study, Study Site shall ensure that the requirements of the Drug Enforcement Administration (DEA), including registration, inspection, and certification, as applicable, are met.

13. Prohibited Research. None of the funds provided hereunder shall be used in a manner contrary to prohibitions set forth in the NIH appropriations act, specifically, the Ban on Funding of Human Embryo Research (Section 510), the Limitation on Use of Funds for Promotion or Legalization of Controlled Substances (Section 511), the Restriction on Distribution of Sterile Needles (Section 505) or the Restriction on Abortions (Section 508) (see grants.nih.gov/grants/guide/notice-files/NOT-OD-03-035.html).

14. Select Agent Research. All research with Select Agents (see 42 CFR 73, and 7 CFR 331, and 9 CFR 121) shall be conducted in accordance with all applicable laws, regulations, and NIH policies.