STAFFING, FUNDING, MATERIALS, and/or EQUIPMENT CONTRIBUTIONS

OF THE PARTIES

*Staffing Contributions:*

VA and NPC Employees will provide scientific staff and other support necessary to conduct the research and other activities described in the Protocol. The Employees/scientific staff will include VA’s CRADA Investigator and technical staff.

 *Funding Contributions:*

**1. Introduction.**

1.1 The compensation set forth in this Appendix B is intended to compensate VA and NPC for participation in the Study and for the VA, NPC and Principal Investigator to perform the additional work necessary to comply with the terms of the Protocol and provide the data to Company in a timely fashion. The compensation includes payment for all activities required by the Protocol, including those for which specific compensation is not set forth in the tables below (e.g. deviations, re-intervention forms, attendance at investigator meetings, and training, as applicable).

1.2 Company will pay the Payee (as that term is defined in the Payment Terms section of this Appendix B) the amounts stated in this Appendix B as compensation for the Protocol related costs to conduct the Study and for the preparation and submission of the Data Forms as outlined in the Protocol and herein. The amounts outlined in this Appendix B are inclusive of all overhead or indirect costs.

2. **Start-Up Costs.**

After written notification by Company that Investigator, VA and NPC have been activated to begin the Study, Company will pay $8,328.00 to be used to cover start-up costs associated with the Study. Such costs shall include, but not be limited to the costs of Study initiation, IRB submission preparation, and administrative services associated with site activation; but shall not include costs related to Protocol training.

**3.** Compensation for Fixed Fees. Collaborator will compensate NPC for fixed fees (“Fixed Fees”) related to the conduct of the Protocol as follows:

| **Activity** | **Description** | **Payment Terms** | **Amount** |
| --- | --- | --- | --- |
| IRB Review Fees, Renewal, and Revision Costs | Actual IRB review fees for the initial Protocol review and IRB fees associated with other reviews required for the Study. | Payment will be made to the IRB after receipt of an invoice from the IRB. | Reasonable IRB fees |
| Study Closure Fee | Fee for the work performed by VA for the closure of the Study at VA. | Payment will be made following Company’s receipt of a detailed invoice from NPC/VA following Study Closure. | $150.00 |
| VA General Counsel Review Fee | Fee for the work performed by VA General Counsel to review the Study, Agreement, and Study budget. | Payment will be made once NPC, VA/, Investigator have been activated to begin the Study. | $1,500.00 |
| IRB Preparation Fee | Fee for the work performed for the preparation and submission of IRB submissions associated with initial review, resubmissions or revisions of the Protocol generated by Collaborator, Informed Consent, annual review, or revisions required for closure of the Study at VA. | Payment will be made following receipt of a detailed invoice from NPC/VA. | $150.00 |

**4. Compensation for Data Forms.**

Company will make payment for Complete Data Forms.

|  |  |
| --- | --- |
| **Data Form** | **Amount** |
| Eligibility Criteria | $1,125.00 |
| Baseline | $118.00 |
| EQ5D | $29.00 |
| Kansas City Cardiomyopathy  | $29.00 |
| Cardiovascular Medications | $55.00 |
| Implant Procedure | $237.00 |
| Randomization | $68.00 |
| Pre-Hospital Discharge | $58.00 |
| Wound Check | $104.00 |
| Limited Follow-up (at 3, 12, 18, 30, 36, 42, 48, 54, and 60 months) | $438.00 |
| 6 Month Comprehensive Follow-up | $575.00 |
| 24 Month Comprehensive Follow-up | $885.00 |
| Long Term Follow-up after 60 Month Follow-up | $136.00 |
| Study Deviation | $55.00 |
| Study Exit | $537.00 |
| Pre-Exit Assessment | $125.00 |
| Subject Death | $385.00 |
| System Modification | $182.00 |
| Crossover | $230.00 |
| Adverse Event | $308.00 |
| Health Care Utilization | $230.00 |
| Device Deficiency | $88.00 |

A “Completed Case Report Form” shall be defined as a Case Report Form with all fields completed, free of any discrepancies, saved as “Complete” and signed by Investigator in the electronic database, unless otherwise specified in writing by Company. Investigator, VA and/or NPC shall inform Company if any tests or services from which data are collected for a Completed Case Report Form are not within the standard of care for Investigator, VA and/or NPC.

**5.** **Compensation for Study Specific Procedures**.

The Study participant or the Study participant’s private or governmental third party payor (“Payor”) are normally responsible for costs that are part of the usual medical care that would have been incurred regardless of the Study participant’s enrollment in the Study. Company understands that the VA does not seek reimbursement from third party Payors for care provided at VA facilities. Company has identified the procedures listed below as procedures that are required only by the Protocol and are not part of standard medical care (“Study Specific Procedures”). VA, NPC and/or Principal Investigator will inform Company if any tests or services identified as Study Specific Procedures are within the standard of care for Principal Investigator, VA and/or NPC. Company will pay for Study Specific Procedures according to the following:

|  |  |
| --- | --- |
| **Test/Procedure** | **Amount** |
| Six Minute Walk Test | $154.00 |
| Echocardiography – if performed after participant is enrolled | $1,038.00 |
| 12 Lead ECG – if performed after participant is enrolled | $140.00 |
| BNP or pro-NT-BNP – if performed after participant is enrolled | $267.00 |
| Pregnancy Test  | $19.00 |
| Serum Creatinine or Glomerular filtration rate - if performed after participant is enrolled  | $50.00 |
| Hepatic Function Panel – if performed after participant is enrolled | $47.00 |
| Hemoglobin – if performed after participant is enrolled | $60.00 |
| Baseline Visit | $204.00 |
| Device Evaluation | $94.00 |
| In-person follow-up evaluation | $163.00 |

Payment for Study Specific Procedures will be made after Company’s receipt of the applicable Complete Data Form or other documentation acceptable to Company. Principal Investigator, VA, and NPC will accept the payments outlined in this Section as payment in full for Study Specific Procedures and will not bill or seek payment for Study Specific Procedures from the Study participant or the Study participant's Payor.

**6. Provision of Study System and Compensation for Implant Related Charges.**

While the System is not investigational, the System is being used in a patient population for which it is not indicated. Company understands that the VA does not seek reimbursement from third party Payors for care provided at VA facilities. Principal Investigator/VA/NPC will agree to cover the costs of the physician and hospital services related to the implant of the System (“Implant Related Services”).

Company will provide a System at no charge for up to a maximum of ten (10) Study participants during the course of the Study. Such no charge System will be appropriately documented through no-charge invoices or credit memos, which are provided to VA/NPC.