

## Fondation Leducq Research Agreement 2013

This agreement (the “Agreement” or “Research Agreement”) is made and entered into as of the first day of \_\_\_\_\_ 2013 by and among the FONDATION LEDUCQ having its registered office at 1, rue Laurent Pichat – 75116 Paris, France, represented by its Scientific Director, Dr. David Tancredi, hereafter referred to as “FLQ”,

AND the following parties

- “Member Institutions” shall mean
  
- “Grantee Institution” shall mean the Member Institution with responsibility for administration of the grant funds as provided below, namely:

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For the purposes of this Agreement, the individuals affiliated with the Member Institutions who are parties to this Agreement are listed as follows:

- “Grantee Coordinator” shall mean
  
- “Other (European or American) Coordinator” shall mean
  
- “Member Investigators” shall mean

(The Grantee Coordinator and the Other Coordinator, European or American as the case may be, may be collectively referred to as “Coordinators.” Member Investigators and Member Institutions may be collectively referred to as “Network Parties.” Network Parties and FLQ may be collectively referred to as “Parties”).

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WHEREAS,

- A. Fondation Leducq is a French non-profit health research foundation, the mission of which is to improve human health through international efforts to combat cardiovascular disease. To this end the Fondation Leducq has created the *Transatlantic Networks of Excellence in Cardiovascular Research Program*, which is designed to promote collaborative research involving centers in North America and Europe in cardiovascular and neurovascular disease. The principal aims of this program are to develop international cardiovascular and neurovascular research networks (each, a “Network”) which achieve a demonstrable collaborative advantage; to advance science in the areas of

cardiovascular and neurovascular disease; to apply the knowledge gained through research by promoting the development of technology and therapeutics to improve human health; and to support the career development of young investigators in cardiovascular and neurovascular research, who will contribute their respective research capacities to the Network program, as set forth in the Proposal described below submitted by the Coordinators.

- B. The Network described in this Agreement has been awarded from FLQ the Research Grant no. 13 CVD 0\_ titled “\_\_\_\_\_” (hereinafter referred to as the “Grant”), based on the proposal dated February 2013 and attached hereto as Exhibit 2 (the “Proposal”), and the revised budget dated \_\_\_\_\_ attached hereto as Exhibit 3 (the “Budget”). (The overall Budget is split among the Member Institutions in US Dollars and Euros, as set forth in Exhibit 4, according to the most appropriate currency for their respective Member Institutions.)

NOW, THEREFORE, THE PARTIES AGREE AS FOLLOW:

Article 1: **TERM**

1.1 This Agreement shall be effective as of [INSERT DATE] for an initial term of eighteen (18) months (“Initial Term”), and may be renewed by FLQ in its sole discretion for two (2) successive renewal periods, (each, a “Renewal Term”, and all such Renewal Terms together with the Initial Term, shall be considered the “Term”) as outlined below. The Initial Term and any subsequent Renewal Terms are designed to correspond to the reporting periods of the Initial Review, the Mid-term Review, and the Final Report, all as described below. Following the Term, a one-year no-cost extended term may be granted by FLQ at its sole discretion pursuant to Section 2.3.

<b>Initial Term</b>	<b>18 months</b>
<b>First Renewal Term</b>	<b>12 months (until mid-term)</b>
<b>Second Renewal Term</b>	<b>30 months</b>
<b>Extended Term</b>	<b>12 months (see section 2.3)</b>

1.2 During the Term, the Network Parties shall use diligent efforts to perform the scientific and educational research work described in the Proposal (the “Project”).

Article 2: **GRANT FUNDS**

2.1 In consideration of the Network’s performance for the Initial Term, and to the extent that the Agreement is renewed as set forth in Section 1.1 for subsequent Renewal Terms, FLQ shall compensate the Network as follows, and as further described in Exhibit 4:

	US Dollars	Euros	Pounds
Year 1			
Year 2			
Year 3			
Year 4			
Year 5			
<u>Total</u>			

2.2 Each party acknowledges and agrees that the above amounts represent the total maximum amount of Grant funds available to the Network under this Agreement for the Initial Term and each possible Renewal Term, covering both the direct and indirect costs of the Network as detailed in Exhibit 4. Although the Initial and Renewal Terms listed in Section 1.1 above, and the reporting and review requirements of Article 5, do not correspond to calendar years, the Budget is drawn up in one-year increments. Budget amounts will be prorated as a function of the relevant budget year 1 thru 5 above wherever necessary because of network reviews occurring in the middle of a fiscal year. FLQ's present commitment is limited to the Grant covering the Initial Term. Each Network Party recognizes that it is not entitled to any claim or cause of action in the event the Grant is not renewed for subsequent Renewal Terms for any reason. Each Network Party does hereby release, acquit and forever discharge FLQ and its Trustees, officers and employees against and from any and all actions, causes of action, claims, demands, costs, whether known or unknown, on account of, in any way growing out of, or resulting from, FLQ's decision, for any reason, not to renew the Network's Grant hereunder beyond the Initial Term or any subsequent Renewal Term, as the case may be.

2.3 In the event that the Network anticipates having Grant funds remaining after the expiration of the Term, the Coordinators may request a single one-year extension to the Term, with no additional cost to FLQ, for purposes of utilizing such remaining funds for the purposes of the Project, subject to the Coordinators submitting, no later than six (6) months prior to the end of the Term, a formal request for such an extension, a budget for utilization of the funds and justification for the expenditures, and their plans for ongoing administration of the Network during such extension period. Any such extensions shall be at the sole discretion of FLQ, and in the event such an extension is not granted, or in the event that funds still remain after such an extension, the disposition of unspent funds will be determined by FLQ in consultation with the Coordinators.

### Article 3: **INVOICE AND PAYMENT OF GRANT FUNDS**

3.1 Within ninety (90) days of each quarterly period during the Term, the Grantee Institution shall send FLQ a detailed invoice corresponding to the work performed by the Network relating to the Project during such quarterly period (each, a “Quarterly Invoice”) in accordance with the procedures described in Exhibit 8. If undisputed by FLQ, FLQ shall pay each such Quarterly Invoice to the Network within thirty (30) days from FLQ’s receipt of such Quarterly Invoice, subject to the yearly maximum Grant amounts set forth in Section 2.1 and Exhibit 4 hereto. Notwithstanding the foregoing, FLQ may elect to prepay certain Grant amounts at its sole discretion.

3.2 The Grant funds need not be physically segregated by a Member Institution in a separate account. Such funds, however, must be shown separately on the Member Institution’s books for ease of reference and verification.

3.3 Upon FLQ’s request, the Grantee Institution shall promptly provide FLQ with any information and documentation to support any Quarterly Invoices.

### Article 4: **RESTRICTIONS ON GRANT FUNDS**

4.1 Should the compensation of any Member Investigator be determined based on the percentage of the time allocated by him (her) to his (her) investigation relating to the Project, the maximum basic annual salary used for the determination shall not exceed US \$ 220,000 (two hundred and twenty thousand U.S. dollars). For the purpose of this clause “basic annual salary” shall mean gross salary without regard to fringe benefits.

4.2 The Grant made hereunder is made only for the scientific and educational work stated in the Proposal, and the Grant funds as well as any interest earned thereon may not be expended for any other work or purpose without FLQ’s prior approval in writing. The Grantee Coordinator shall notify FLQ if there are any changes in the Grantee Coordinator’s plans regarding the scientific and educational work stated in the Proposal. Any change in the direction of the studies or Budget must be submitted for review and approval in accordance with Section 6.3. Subject to Section 6.3, it is understood that the Grant funds will be used substantially in accordance with the submitted Budget attached hereto as Exhibit 4. Any Grant funds not expended or committed during the Term for the scientific and educational work stated in the Proposal shall be promptly returned to FLQ except as provided in Section 2.3. If FLQ becomes aware that the Grant funds are not being used for the scientific and educational work stated in the Proposal, FLQ reserves the right to be reimbursed for the amounts so diverted, and shall have the right to withhold any future Grant payments and/or terminate this Agreement pursuant to Section 12.2 below.

4.3 The Grant funds may not be used by any Network Party to attempt to influence any legislation or the outcome of any public election; to carry on, directly or indirectly, any voter registration drive; to make grants to individuals or to other organizations; to undertake any commercial venture or any activities with a non-charitable, non-scientific or non-educational purpose; or for any other purpose not specifically described herein. Unless

otherwise approved, travel expenses must be limited to travel to and from Member Institutions, or to and from other mutually agreed-upon convenient meeting locations (including, e.g., after a national or international conference).

4.4 Each Member Institution shall, with respect to each individual Member Investigator affiliated with it, comply with the FLQ Policy on Objectivity in Research by Grant Applicants and Grantees, a copy of which is attached to this Agreement as Exhibit 9 (the “COI Policy”), subject to the following exceptions:

(a) If a Member Institution has in place, and is willing to enforce, a comparable policy addressing the same subject matter as the COI Policy, such Member Institution can seek a waiver from the FLQ to apply such a policy instead of the COI Policy, which waiver will not be unreasonably withheld;

(b) If a Member Institution does not have the willingness or administrative capacity to enforce the COI Policy or a comparable policy, it shall so notify FLQ, in which case FLQ will require that all individual Member Investigators affiliated with such Member Institution enter into a written commitment directly with FLQ for the administration of the COI Policy.

Any waivers or agreements described in 4.4(a) or (b) above must be entered into in writing prior to the effective date of this Agreement or, if later, prior to the effective date that a Member Institution becomes a Party to this Agreement.

## Article 5: **FLQ REVIEW OF NETWORK PERFORMANCE**

**THE NETWORK’S PERFORMANCE WILL BE REVIEWED AT THE END OF THE INITIAL TERM AND AGAIN AT THE MIDTERM (AT THE END OF THE FIRST RENEWAL TERM).** No additional funds are made available to Member Investigators for travel in connection with the Initial Review and Mid-term Review, which travel (as defined below) may be funded by Grant funds.

5.1 The first network review (“Initial Review”) will be a scientific workshop held in conjunction with the regular spring meeting of the Scientific Advisory Committee (“SAC”) of FLQ. The two Coordinators, and possibly one or two additional Member Investigators, will be invited to present their progress and plans at this workshop attended by the SAC and the leaders of the other networks. If the Initial Review occurs after the scheduled onset of the First Renewal Term, the Initial Term shall be extended until the conclusion of such Initial Review, with all parties respecting and applying, on a pro-rated basis, the provisional budget and plans for the First Renewal Term, as agreed to in this Research Agreement.

5.1.1 The objective of this Initial Review will be to describe progress made in the organization of the Network. This will include a description of the persons hired, communication tools, minutes and summaries of Network meetings, updated research plans including projected milestones, and any proposed rebudgeting. The oral presentations by the two Coordinators and any other Members shall be preceded by the Initial Progress Report (as further described in Section 6.4

below), submitted to the SAC by the Coordinators four (4) weeks before the First Year Review.

5.1.2 The goal of these workshops will be to: 1) assure FLQ that the organization of the Network as outlined in the Proposal is proceeding successfully; 2) inform FLQ of any major modification in the research plan or personnel; 3) establish communication among the several networks to encourage discussion and knowledge transfer about network management.

5.2 The mid-term review (“Mid-Term Review”), if applicable, will be a site visit at a regularly scheduled Network meeting, conducted by one member of the SAC, one external scientific consultant, and representatives from the FLQ, and will be scheduled to take place at the conclusion of the first Renewal Term, at the midpoint of the five-year Grant. The FLQ and the Coordinators will endeavor to fix, well in advance, and at a mutually convenient time, a date for the site visit. If the Mid-Term Review is held during the Second Renewal Term (sometime after the halfway mark of work performed under the five-year Grant), the first Renewal Term shall be extended until the conclusion of the Mid-Term Review, with all Parties respecting and applying, on a pro-rated basis, the provisional budget and plans for the Second Renewal Term, as agreed to in this Research Agreement. All Member Investigators agree to be present at the Mid-Term Review, if requested by the FLQ. The site visit will be a full day meeting and will consist of a complete review of the entire Project including scientific progress, Network organization, exchange of personnel, training, Network meetings, budgetary matters, and proposed plans for the remaining term of the Grant. The Mid-Term Review Report (as further described in Section 6.4 below) shall be submitted to the SAC by the Coordinators thirty (30) days prior to the Mid-Term Review.

5.2.1 FLQ’s reviewers will report their findings to the full SAC prior to the next regularly scheduled SAC meeting. Any further renewal of this Agreement will be contingent on a satisfactory review of the Mid-Term Review Report and site visit report by the SAC.

## Article 6: **COORDINATOR RESPONSIBILITIES**

6.1 The Grantee Coordinator shall be primarily responsible for communication between the Network and FLQ, in consultation with the Other Coordinator.

6.2 The Coordinators shall represent the Network with respect to any and all technical matters relating to and in connection with the performance of the Project. The Coordinators shall be responsible for work and organization relating to the Project by all Network Parties.

6.3 Subject to FLQ’s prior written approval, the Coordinators may mutually decide to: (i) add additional Member Investigators (and their respective Member

Institutions), provided that any such additional Member Investigators and their respective Member Institutions execute the appropriate Acknowledgment attached hereto as Exhibit 1 ; (ii) remove Member Investigators and their respective Member Institutions if no affiliated Member Investigator remains in the Network; (iii) modify the Proposal attached hereto as Exhibit 2; and (iv) modify the Budgets attached hereto as Exhibits 3 and 4. For budgetary changes involving reallocations within a Member Institution that do not materially affect the Project, and that do not involve changes of greater than 20% of the annual institutional budget, prior approval of the FLQ will not be necessary, although the Coordinators must inform the FLQ through the normal reporting mechanism. Budgetary changes that are approved by the Fondation Leducq do not require a formal amendment of this agreement.

6.4 The Coordinators shall be responsible for submitting a progress report (each, a “Progress Report”) to the SAC at the conclusion of each of the Terms listed in section 1.1:

- (a) the Initial Progress Report, at least thirty (30) prior to the Initial Review;
- (b) the Mid-Term Progress Report, at least thirty (30) days prior to the Mid-Term Review meeting;
- (c) the Year 4 Progress Report (an abbreviated report providing an update on publications and member activities) within thirty (30) days of the date marking four (4) years of work performed under the Grant; and
- (d) the Final Report within ninety (90) days after the conclusion of the last Renewal Term.

Each Progress Report will include a separate financial report (the “Financial Report”) that compares actual spending with budgeted spending following the template provided in the Billing Chart appended to this Agreement (see Exhibit 11). Although the schedule of submission for these Progress Reports does not follow the yearly budget cycle, for purposes of communication with FLQ, the budget should be expressed as an annual budget. Where budget reports require the inclusion of the budget or expenses of fractions of a year, amounts should be prorated based on the relevant annual budget. Each Report shall include a hard copy or a PDF file of any reports, publications, catalogues, or other materials prepared by any Network Party in connection with the Project.

6.4.1 Each Financial Report must be attested to by an officer of the Grantee Institution or its certified public accountant and must reflect all of the categories of expenditures (including salaries, travel and supplies) detailed in the Budget.

6.4.2 Each Progress Report shall consist of any information required to be disclosed by any Network Party to the Coordinators pursuant to Section 9.3, a few pages of description of the work performed in connection with the Project, the goals accomplished and the progress made by the Network toward achieving the work described in the Proposal and for which the Grant was made. Each Progress Report shall also list all other sources of funding to each Network Party relating to the Project hereunder, and all Inventions reported to Coordinators under Section 9.3

below. A template for such Progress Reports will be provided to the Coordinators well in advance of the date of submission.

6.5 FLQ retains the right to request additional information relating to the Project as it deems necessary.

6.6 During the Term hereof and for a period of three (3) years thereafter, the Coordinators shall periodically inform FLQ, upon request, of any award or honor granted to any Network Party or to any other person involved in the Project.

6.7 FLQ has selected the Coordinators to act as the scientific and administrative leaders of the Network, and as such, they must at all times during the Term be able to carry out their duties in a diligent and professional manner. If, at any time, FLQ determines, in its sole discretion, that either Coordinator has become unable to fulfill his or her duties in all respects, either permanently or for an extended period, FLQ shall have the right, upon written notice, to either (i) replace such Coordinator (and his or her Member Institution if no other affiliated Member Investigator remains in the Network) with another qualified individual affiliated with an institution that is willing to become a Member Institution (and the Grantee Institution if the replaced Coordinator was the Grantee Coordinator), or (ii) if FLQ determines, in its sole discretion, that such Coordinator performs such a key role in the Network that he or she cannot be replaced without compromising the purposes of the Project, FLQ may terminate this Agreement and the Network upon notice given pursuant to Section 12.2. FLQ intends to exercise this right only rarely and under compelling circumstances, such as (and without limitation) by reason of death, serious illness, transfer to a position at a new institution which does not wish to support the Network by becoming a Member Institution or Grantee Institution, as the case may be, or removal from professional responsibilities at his or her institution for disciplinary or other reasons. In all cases where FLQ decides that a Coordinator must be replaced, FLQ will seek the advice of remaining Network Parties regarding the selection of an appropriate replacement, but FLQ will have the final decision on the selection of a replacement Coordinator.

## Article 7: **CONTRACT ADMINISTRATORS**

7.1 Dr. David Tancredi shall represent FLQ for the purpose of this Agreement and shall be responsible for any and all matters in connection with the construction and administration hereof and for the collection of Progress Reports to be submitted to the FLQ Scientific Advisory Committee.

## Article 8: **ACKNOWLEDGMENT AND PUBLICITY**

8.1 Each Network Party agrees to be listed in the FLQ website and in publications consistent with such Network Party's policies. Each Network Party agrees to reasonably



cooperate with FLQ in promoting FLQ's goals and objectives, and upon FLQ's request, shall provide brief statements regarding such Party's participation in the Network. Each Network Party shall acknowledge FLQ for the Grant made hereunder through publications/presentations and/or press releases mentioning FLQ's support and contribution to the scientific and educational work performed by the Network and the results thereof, whenever possible and/or appropriate, in a form that is agreeable to FLQ and consistent with such Network Party's policies. FLQ's preferred acknowledgement for written reports is: "Supported by a grant from the Fondation Leducq." Failure to acknowledge support of the FLQ may result in discontinuation of support.

8.2 **With the exception of professional publications such as journal articles, books, abstracts, and editorials**, the dissemination of which requires no prior authorization from FLQ, all information intended for the public domain, including but not limited to press releases, formal public statements, written references in public documents and structured publicity in general, which is issued by Member Investigators or their respective Member Institutions, and which mentions or refers to the FLQ in connection with the grant or the research under the grant, must be cleared in advance by the FLQ office.

8.3 Each Network Party agrees to report all future publications related to the Project, and to acknowledge FLQ's support in such publications.

8.4 FLQ will include information about this Grant periodically on its website and in its own public releases and reports. FLQ may include in such releases and reports any publications, information from interim reports or catalogs already in the public domain, or, with the consent of the Coordinators, other materials prepared by any Network Party in connection with the Grant. The Grantee Coordinators shall, from time to time upon FLQ's request, prepare a short summary (no more than 10 slides) of Project results for public display on the FLQ website.

8.5 The Coordinators agree, if requested by FLQ, to attend or participate in one or more future symposiums or scientific events organized by FLQ at FLQ's expense. This participation may include a presentation of the current status of the Project and its new findings.

## Article 9: **OWNERSHIP AND INTELLECTUAL PROPERTY**

9.1 Member Institution shall obtain title at the end of the Term to any equipment costing greater than USD 10,000 purchased by that Member Institution using Grant funds for the performance of the scientific and educational work related to the Project hereunder, unless, during the Term, the Member Investigator for whose laboratory such equipment was purchased moves to another Member Institution as contemplated by [Article 14](#), in which case such Member Investigator shall be entitled to transfer such equipment to his or her new Member Institution. The proposed purchase of any equipment using Grant funds, but not listed in the Budget, shall require FLQ's prior written approval.

9.2 Each Member Investigator represents that Exhibit 5 accurately sets forth all patents and patent applications relating to the subject matter of the Project in which such Member Investigator is named as an inventor.

9.3 Both during and after the Term, each Network Party shall report to FLQ and the Coordinators all inventions, whether patentable or not, arising out of research supported in whole or in part by FLQ which are reduced to practice, the subject of a patent application and/or which are licensed or otherwise commercialized (“Inventions”). FLQ may terminate this Agreement pursuant to Section 12.2 with respect to any Network Party who breaches its obligations under this Section 9.3. At a minimum, during the Term, each Network Party shall notify the Coordinators at least thirty (30) days prior to the date each Progress Report is to be submitted under Section 6.4 of any and all of the following events related to the Project: (a) submission of an Invention disclosure; (b) filing of a patent application; (c) patent issuance; (d) licensing or other commercial transactions; and (e) termination of licenses or disputes with licensees. Upon request by FLQ, Network Parties agree to supply FLQ with a copy of any invention disclosure that is supported in whole or in part by FLQ. Unless and until published these documents shall constitute Proprietary Information, and shall be governed by the terms of Article 13, herein. At a minimum, after the Term and for so long as any Inventions are subject to any intellectual property protection, each Network Party shall notify FLQ of any and all of the events described in the preceding sentence on an annual basis, commencing with the first anniversary of expiration or termination of the Term.

9.4 FLQ will defer to Member Institutions’ established and applicable patent, intellectual property or technology transfer policies and procedures relating to disclosure, protection and commercialization of Inventions, subject to the following:

9.4.1 FLQ’s determination that such policies and procedures are consistent with FLQ’s goals and principles, which policies and procedures, whether or not specifically adopted for purposes of this Grant, shall be deemed consistent therewith if they provide for (a) publication of research results; (b) assignment of Inventions made by Members to the applicable Member Institution;<sup>1</sup> and (c) an obligation to diligently exploit any Inventions for the benefit of the public, through licensing or other means, to the extent feasible;

9.4.2 each Member Institution’s agreement not to abandon any patent application or other intellectual property protection relating to any Invention without sufficient prior notification to FLQ to enable such application or protection to be assigned to FLQ, unless prohibited by applicable law, regulation, or terms of another applicable grant;

9.4.3 each Member Institution’s agreement not to assign its rights, except to an invention management organization, in which case such organization

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<sup>1</sup> In the case of Members who are employees of the Howard Hughes Medical Institute (“HHMI”), it is acknowledged by FLQ that any Inventions will be first assigned to HHMI and then re-assigned by HHMI to the applicable Member Institution, subject to the HHMI Intellectual Property Policy.

shall agree to be bound by the applicable terms of this Agreement, relating to any Invention without FLQ's prior written consent; and

9.4.4 the performance of each Network Party's obligations as described in this Agreement, including without limitation the reporting obligations described in Section 9.3 above.

9.5 If a Member Institution has no such established and applicable patent, intellectual property or technology transfer policy, then FLQ shall have the right to determine the disposition of rights in the applicable Inventions in accordance with this Article 9 and Exhibit 7.

9.6 FLQ shall participate in the income derived directly or indirectly from commercialization of any and all Inventions. FLQ's share of such income shall be negotiated in good faith by FLQ and the applicable Member Institution within one (1) year after reporting of the Invention to FLQ pursuant to Section 9.3. The amount of FLQ's participation shall be guided by the principle that FLQ's sharing of income shall be proportionate to FLQ's proportion of support for the work or research giving rise to the Invention. In the event that any income is due to FLQ pursuant to this Section 9.6, FLQ shall designate the recipient to whom any such payment shall be made on its behalf.

9.7 In the event that a Network Party intends to form a company to commercialize an Invention, it shall consider in good faith offering FLQ, or another party identified by FLQ, on terms comparable to those offered to other investors, an opportunity to invest in any such company.

9.8 If no effective steps have been taken within three (3) years of issuance of a patent or grant of a license, whichever occurs first, relating to any Invention, or other clear determination of commercial value, to bring the Invention to practical or commercial application on terms that are reasonable in circumstances, the applicable Member Institution and FLQ shall discuss in good faith what steps, if any, should be taken to accomplish the practical or commercial application of the Invention. Such steps may include (a) assignment of the Invention to FLQ, unless prohibited by applicable law, regulation, or terms of another applicable grant; (b) cancellation of any outstanding exclusive licenses; (c) granting of non-exclusive licenses on a royalty-free basis or on other terms that are reasonable in the circumstances; or (d) other reasonable disposition of such rights in and to the Invention.

#### Article 10: **REPRESENTATIONS, RESPONSIBILITIES AND LIABILITY**

10.1 Each Network Party represents and certifies that: (a) it will perform all activities under this Agreement in accordance with generally accepted standards of sound research and medical practices, and all applicable laws, rules, and regulations, including without limitation all applicable laws, rules and regulations of the country where the activities are performed, and any other applicable jurisdiction governing the conduct of the activity; (b) for all research conducted in the United States it will perform any human or animal clinical testing and experimentation hereunder, if authorized by FLQ in accordance with Section 10.3

below, in accordance with Good Clinical Practices as stated in the guideline issued by the International Conference on Harmonization found at 62 Fed. Reg. 25692 (May 9, 1997), all applicable provisions of the U.S. Federal, Food, Drug and Cosmetic Act and its implementing regulations including 21 CFR Parts 50, 56 and 312, and with all applicable policies for the protection of human subjects, including those contained in the “Common Rule”, 45 CFR Part 46; (c) for all research conducted outside the United States it will perform any human or animal clinical testing and experimentation hereunder, if authorized by FLQ in accordance with Section 10.3 below, in accordance with counterpart Good Clinical Practices to those referenced in Section 10.1(b) as implemented in the applicable jurisdiction; (d) neither such Network Party nor any person employed by such Network Party has been debarred under Section 306(a) or Section 306(b) of the Federal Food, Drug and Cosmetic Act; (e) it maintains sufficient liability insurance coverage for its activities relating to the Project hereunder, and to fulfill all of its obligations to FLQ as set forth in this Agreement; and (f) only such non-Member individuals who are obligated to assign to a Member Institution their right, title and interest in and to any Invention shall be allowed to contribute to the Project hereunder. Each Member represents and certifies that he (she) is obligated to assign to his (her) respective Member Institution his (her) right, title and interest in and to any Invention,<sup>2</sup> or in the event that he (she) is not so obligated, that he (she) agrees to sign and be bound by the Agreement of Individual Inventor in the form attached as Exhibit 7.

10.2 Each Network Party hereby acknowledges that FLQ’s participation is solely as the source of funds for the activities to be conducted under this Agreement, and that each Network Party assumes full responsibility for any claims by non-Network Parties that may arise from the acts or omissions of such Network Party in the performance of this Agreement. FLQ shall have no liability for any such claims except to the extent any such claims arise from the negligence or intentional misconduct of FLQ.

10.3 Each Network Party agrees that it will not conduct any clinical studies in humans under this Agreement without first obtaining the prior written consent of FLQ. Such consent shall not be unreasonably withheld, provided that the Network Party provides evidence satisfactory to FLQ that it (or, in the case of Members, its Member Institution) maintains adequate insurance policies against any claims which may arise from such studies and that FLQ has been expressly named as an additional insured under such policies.

## Article 11: **AUDIT AND INSPECTION**

11.1 At any time during the Term hereof and subject to reasonable prior notice, FLQ personnel shall have access to the Grantee Institution’s premises to observe Grantee Coordinator’s work relating to the Project, books of accounts relating to the Project, and copies of all Reports, and all supporting documentation relating thereto, for inspection purposes.

## Article 12: **TERMINATION**

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<sup>2</sup> For HHMI investigators, see section 9.4.1.

12.1 Subject to FLQ's prior written approval, the Coordinators may mutually decide to terminate this Agreement without cause with respect to any Network Party effective upon written notice to the applicable Member(s) and their respective Member Institution(s) pursuant to Section 6.3 above.

12.2 FLQ may terminate this Agreement with respect to any Network Party upon written notice in the event of a material breach of this Agreement by such Network Party that is not cured within ninety (90) days of written notice from FLQ; except that FLQ may terminate this Agreement with respect to any Network Party, effective immediately upon written notice from FLQ, in the event that such Network Party breaches its representations, certifications or obligations as set forth in Article 10. In the event of termination of a Network Party hereunder, FLQ shall have the right, upon ninety (90) days' written notice to all Network Parties, to terminate this Agreement in its entirety if such termination makes completion of the Project no longer feasible and a qualified substitute Network Party cannot promptly be engaged.

12.3 Pursuant to Section 6.7(ii), FLQ may terminate this Agreement in its entirety upon ninety (90) days' written notice to all Network Parties in the event that it determines that a Coordinator can no longer fulfill his or her responsibilities to the Network, and FLQ further determines that he or she cannot be replaced without compromising the purposes of the Project.

12.4 FLQ may terminate this Agreement in its sole discretion in the event of any material disagreement between the Coordinators relating to the subject matter of Section 6.3 that is not resolved by agreement of the Coordinators within a reasonable period of time. During any such period of unresolved material disagreement between the Coordinators, FLQ may elect in its sole discretion to suspend the provision of any Grant funds to the Grantee Institution or any other Network Party.

12.5 Articles 8, 9, 10, 13 and 15, and any agreement entered into in substantially the form of Exhibit 7, shall survive any expiration or termination of this Agreement.

12.6 In the event of early termination of this Agreement, or of a Network Party's participation in the Network, other than for cause pursuant to Section 12.2, any Network Party so terminated shall be reimbursed by FLQ for all reasonable expenses incurred and costs reasonably committed to be expended under any uncancellable commitments made as of the effective date of termination. In the event of termination of a Network Party for cause under Section 12.2, such Network Party shall reimburse FLQ for the cost of any equipment purchased by such Network Party prior to termination and which was not materially used to advance the purposes of the Project.

12.7 Each Network Party may terminate this Agreement upon 30 (thirty) days written notice to FLQ. In such an event, FLQ will reimburse the Network Party for reasonable expenses related to the Project, but will not honor long term or extraordinary uncancellable commitments made ninety (90) days or less before the date of the written notice.

## Article 13: **PROPRIETARY INFORMATION AND CONFIDENTIALITY; OBLIGATION TO SHARE DATA**

13.1 As used in this Agreement, the term “Proprietary Information” shall mean all confidential or proprietary information or materials designated as such in writing by a disclosing Party (the “Disclosing Party”), whether by letter or by the use of an appropriate proprietary stamp or legend, prior to or at the time any such materials or information are disclosed by the Disclosing Party to a receiving Party (the “Recipient”). Materials or information which are orally or visually disclosed to a Recipient, or are disclosed in writing without an appropriate letter, proprietary stamp or legend, shall nevertheless constitute Proprietary Information if the Disclosing Party, within thirty (30) days after such disclosure, delivers to each Recipient a written document or documents describing in summary terms such materials or information and referencing the place and date of such oral, visual, or written disclosure and the names of the representatives of each Recipient to whom the disclosure was made.

13.2 Each Recipient agrees that all Proprietary Information disclosed to it shall be maintained in confidence, and shall be used only for the purposes of this Agreement. Such obligation of confidentiality shall not apply to information which a Recipient can demonstrate: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no fault of the Recipient; (iii) was known to the Recipient prior to the disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Recipient by a third party which was not under an obligation of confidence to the Disclosing Party with respect thereto; (v) was independently developed by the Recipient without use of any Proprietary Information. In addition, any Recipient shall have the right to disclose Proprietary Information to the extent necessary to comply with applicable laws, government regulations, or court orders, provided that such Recipient provides prior written notice of such obligation to the Disclosing Party to allow the Disclosing Party to take lawful actions to avoid and/or minimize the extent of such disclosure. These obligations of confidentiality shall continue for three (3) years after the termination of this Agreement.

13.3 It is a fundamental objective of FLQ in establishing the Network to advance scientific and clinical knowledge through the efforts of the Network Parties in conducting the Project. All Network Parties acknowledge this objective and agree that all data resulting from research conducted under the Project will not be considered Proprietary Information and will be promptly shared with FLQ and other Network Parties, consistent with prudent practices to ensure that premature disclosure does not adversely affect the ability to file applications for potentially patentable inventions. In addition, all Network Parties acknowledge that significant developments in the course of such research will be made public, through peer-reviewed journals, presentations at academic and scientific conferences, and the like, subject to credit to FLQ to the extent provided in Section 8.2.

## Article 14: **TRANSFER OF A MEMBER’S AFFILIATION TO A NEW INSTITUTION**

14.1 In the event that a Member (including a Coordinator) intends to transfer his or her primary professional affiliation to a new institution that is not a current Member

Institution of the Network and wishes to remain a Member, he or she shall give at least ninety (90) days' prior written notice to FLQ and to the Coordinators (or to the remaining Coordinator if the transferring Member is him-or her- self a Coordinator) as to the institution to which he or she is transferring his or her affiliation (the "Notice Period"). During the Notice Period, FLQ and/or the Coordinators will discuss with the Member's existing Member Institution the use of FLQ funding by the departing Member during the Notice Period, and shall arrange for a winding-down of the use of such FLQ funds for the Project. During the Notice Period, the said Member Institution may, with the written approval of FLQ, also utilize certain of such funds to pay for reasonable expenses incurred and costs reasonably committed to be expended under any uncancellable commitments by the Member Institution and/or the departing Member on behalf of the Project prior to commencement of the Notice Period. At the end of the Notice Period, all remaining FLQ funds in the possession of the departing Member or the Member Institution will be returned to FLQ. Upon the departure of the Member, the Member Institution will cease to be a Member Institution of the Network unless another Member of the Network remains affiliated with the Member Institution.

14.2 During the Notice Period FLQ and the Coordinators shall evaluate whether the new institution with which the Member will become affiliated is suitable to become a Member Institution.

14.2.1 If the decision is positive, FLQ will require the new institution to agree in writing to be bound by the terms of this Agreement, effective upon the Member's affiliation with it, the institution will thereupon become a Member Institution of the Network. FLQ and the Coordinators will make arrangements for the FLQ funds that had been allocated to the Member for use in the Project to be paid to the new Member Institution, and provide a schedule for such payments.

14.2.2 If the decision is negative, FLQ will so notify the Member and his new institution, and the Member will thereupon cease to be a Member of the Network. FLQ and the Coordinators will determine how to allocate the funds that had previously been committed to the said former Member.

14.3 Any former Member Institution under this Article shall have no claim against FLQ for any further funding after the departure of the Member at the end of the Notice Period.

14.4 FLQ will notify in writing all remaining Members and Member Institutions of the outcome of any such transfer, as described above, and will, if the outcome results in a new Member Institution, include in such notice a copy of the new Member Institution's agreement to be bound by the terms of the Agreement.

## Article 15: **GENERAL**

15.1 Any dispute among any Parties with respect to the interpretation, construction and performance of this Agreement which cannot be settled amicably may be resolved in

accordance with laws of the country of the respondent to a claim by a Party. Nothing that in this Article shall prevent a Party seeking an injunction in any court of competent jurisdiction.

15.2 This Agreement, including all Exhibits attached hereto, represents the entire agreement of the Parties relating to the subject matter hereto, and supersedes all previous discussions, representations, and understandings related to the subject matter of this Agreement. To the extent the terms of this Agreement and the terms of an Exhibit hereto conflict, this Agreement shall govern. Any amendment to this Agreement or of any Exhibits hereto shall be binding only if they are reflected in a document signed by or on behalf of all Parties, *provided, however*, that in light of the number of Parties and the resulting difficulty of obtaining signatures from all Parties, certain amendments to this Agreement may be made without obtaining all such signatures, as follows:

15.2.1 In the case of additional Members (and their respective Member Institutions) being added to the Network pursuant to Section 6.3 and Exhibit 1, the signatures of the new Member, of his or her Member Institution, and of the Coordinators on a document in the form of Exhibit 1 shall be sufficient to effect the addition of such party to the Network, notice of which shall be given to the existing Network Parties.

15.2.2 In the case of Members and/or their respective Member Institutions being removed from the Network pursuant to Section 6.3, a notice to the remaining Network Parties signed by the Coordinators and FLQ shall be sufficient to effect such removal.

15.2.3 In the case of replacement of a Coordinator by FLQ pursuant to Section 6.7, a document under which the new Coordinator and his or her Member Institution agree to be bound by the terms of this Agreement, and signed by FLQ, shall be sufficient to effect the replacement of such Coordinator, notice of which shall be given to the Network Parties.

15.2.4 In the case of an amendment to this Research Agreement between FLQ and a single Member Institution to allow such Member Institution to comply with specific local policies, and where such amendment concerns no Network Parties other than FLQ and the Member Institution, a side letter Agreement signed by representatives of FLQ and the Member Institution shall be sufficient to effect such amendment.

15.3 The provisions of this Agreement are severable and if any of the provisions hereof are held to be invalid, illegal or unenforceable, in whole or in part, the remaining provisions of this Agreement shall remain binding and enforceable by and among the parties.

15.4 No waiver of any portion of this Agreement shall be effective unless in writing signed by the waiving party. FLQ's failure at any time to require performance by any Network Party of any provision shall in no way affect FLQ's right to enforce that or any other provision of this Agreement. No waiver of any breach of this Agreement shall constitute a waiver of any subsequent breach of the same or any other provision of this Agreement.



15.5 The Parties are independent contractors under this Agreement, and nothing herein shall be construed to create a partnership or joint venture relationship among the Parties. No Party shall have authority to enter into agreements of any kind on behalf of any other Party or the power or authority to bind or obligate any other Party in any manner to any third party.

15.6 No Network Party shall assign this Agreement nor any of its rights, interests or obligations hereunder, nor shall it sub-contract in whole or in part the work to be performed hereunder without the prior written approval of FLQ.

15.7 This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. It shall not be a condition to the effectiveness of this Agreement that each party shall have executed the same counterpart.

15.8 All notices permitted or required by this Agreement shall be writing and in the English language and may be delivered by messenger or may be sent by registered mail, return receipt requested addressed as set forth on Exhibit 6. Any such notice shall be deemed given upon receipt thereof by the recipient.

REMAINDER OF PAGE LEFT BLANK

IN WITNESS WHEREOF, the Parties hereto agree to participate in this Research Agreement N°13 CVD 0\_ in accordance with the terms and conditions contained herein (including all Exhibits), and have caused this Agreement to be executed by their duly authorized representatives as of the date first above written. The patents and patent applications related to the subject matter of the Project in which any Member is named as an inventor have been duly listed in Exhibit 5.

**FONDATION LEDUCQ:**

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

**Name: David Tancredi, Scientific Director, Fondation Leducq**

**PARTIES**

**GRANTEE INSTITUTION:**

\_\_\_\_\_  
**Name:**

**MEMBER INSTITUTIONS:**

\_\_\_\_\_  
**Name:**

\_\_\_\_\_  
**Name:**

\_\_\_\_\_  
**Name:**

\_\_\_\_\_  
**Name:**

\_\_\_\_\_  
**Name:**

Name:

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**GRANTEE COORDINATOR:**

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**OTHER COORDINATOR:**

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**MEMBER INVESTIGATORS:**

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EXHIBIT 1

ACKNOWLEDGMENT FOR ADDITIONAL MEMBER

**[Insert name of additional Member]** and **[insert name of additional Member Institution]** acknowledge that they have read the Research Agreement dated [insert date] relating to the **[insert title of Network]** (the "Network"), and agree to join such Network as an additional Member subject to all of the terms and conditions set forth in the Research Agreement. This Acknowledgment shall be effective as of **[insert effective date]**.

**MEMBER:**

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

**MEMBER INSTITUTION:**

[Insert name of Member Institution]:

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

**GRANTEE COORDINATOR:**

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

**OTHER COORDINATOR:**

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

EXHIBIT 2

PROPOSAL

EXHIBIT 3

BUDGET

EXHIBIT 4

INSTITUTIONAL BUDGET ALLOCATIONS.

EXHIBIT 5

PATENTS AND PATENT APPLICATIONS  
IN WHICH ANY MEMBER IS NAMED AS AN INVENTOR



EXHIBIT 6

ADDRESSES OF PARTIES

EXHIBIT 7

MODEL AGREEMENT OF INDIVIDUAL INVENTOR

This model agreement of individual inventor (the “Agreement”) is made and entered into as of the day of \_\_\_\_\_, 2013 by and among the FONDATION LEDUCQ having its administration offices at 1, rue Laurent Pichat – 75116 Paris, France (“FLQ”), and \_\_\_\_\_ (“Member”), an **individual**, with an address at \_\_\_\_\_ having a professional appointment at \_\_\_\_\_ (“Institution”), a research institution with an address at \_\_\_\_\_.

WHEREAS,

A. The Member is a member of a Network funded by FLQ, 13 CVD \_\_, pursuant to a Research Agreement dated \_\_\_\_\_, 2013 (the “Research Agreement”), whose purpose is to accomplish, together with other individual and institutional members, a specific scientific research project described in the Research Agreement. As a condition of such funding, FLQ requires that all individual Members either (a) agree to assign to his or her Member Institution his or her rights in any Invention (as defined below) or (b) enter into an agreement directly with FLQ in which he or she agrees to manage any such Invention in a manner consistent with Article 9 of the Research Agreement;

B. Under the policies of the Institution with which Member is affiliated, the Member has no obligation to assign Inventions to the Institution and is free to dispose of any Inventions in his or her discretion;

C. Member has therefore agreed to manage any Inventions in accordance with this Agreement; and

D. All capitalized terms shall have the meanings set forth in the Research Agreement.

NOW, THEREFORE, THE PARTIES AGREE AS FOLLOWS:

**Article 1: Term**

1.1 This Agreement shall be effective as of \_\_\_\_\_ and shall continue for the term of the Research Agreement, subject to survival of certain provisions as stated below.

**Article 2: Ownership and Intellectual Property**

2.1 Both during and after the Term, Member shall report to FLQ and the Coordinators (as defined in the Research Agreement) all inventions, whether patentable or not, arising out of research supported in whole or in part by FLQ which are reduced to practice, subject of a patent application and/or which are licensed or otherwise commercialized (“Inventions”). FLQ may terminate the Research Agreement pursuant to Section 12.2 thereof with respect to Member if he or she breaches Member’s obligations under this Section 2.1. At a minimum, during the Term,

Member shall notify the Coordinators at least thirty (30) days prior to the date each Progress Report is to be submitted under Section 6.4 of the Research Agreement of any and all of the following events related to the Project: (a) submission of an Invention disclosure; (b) filing of a patent application; (c) patent issuance; (d) licensing or other commercial transactions; and (e) termination of licenses or disputes with licensees. At a minimum, after the Term and for so long as any Inventions are subject to any intellectual property protection, Member shall notify FLQ of any and all of the events described in the preceding sentence on an annual basis, commencing with the first anniversary of expiration or termination of the Term.

2.2 Member agrees not to abandon any patent application or other intellectual property protection relating to any Invention without sufficient prior notification to FLQ to enable such application or protection to be assigned to FLQ, unless prohibited by applicable law, regulation, or terms of another applicable grant.

2.3 Member agrees not to assign its rights, except to an invention management organization, in which case such organization shall agree to be bound by the applicable terms of this Agreement, relating to any Invention without FLQ's prior written consent.

2.4 FLQ shall participate in the income derived directly or indirectly from commercialization of any and all Inventions. FLQ's share of such income shall be negotiated in good faith by FLQ and the Member within one (1) year after reporting of the Invention to FLQ pursuant to Section 2.1. The amount of FLQ's participation shall be guided by the principle that FLQ's sharing of income shall be proportionate to FLQ's proportion of support for the work or research giving rise to the Invention. In the event that any income is due to FLQ pursuant to this Section 2.4, FLQ shall designate the recipient to whom any such payment shall be made.

2.5 In the event that Member intends to form a company to commercialize an Invention, it shall consider in good faith offering FLQ, on terms comparable to those offered to other investors, an opportunity to invest in any such company.

2.6 If no effective steps have been taken within three (3) years of issuance of a patent or grant of a license, whichever occurs first, relating to any Invention, or other clear determination of commercial value, to bring the Invention to practical or commercial application on terms that are reasonable in the circumstances, the Member and FLQ shall discuss in good faith what steps, if any, should be taken to accomplish the practical or commercial application of the Invention. Such steps may include (a) assignment of the Invention to FLQ, unless prohibited by applicable law, regulation, or terms of another applicable grant; (b) cancellation of any outstanding exclusive licenses; (c) granting of non-exclusive licenses on a royalty-free basis or on other terms that are reasonable in the circumstances; or (d) other reasonable disposition of such rights in and to the Invention.

2.7 This Article 2 shall supersede and replace Article 9 of the Research Agreement with respect to the Member.

### Article 3: GENERAL

3.1 This Agreement, together with the Research Agreement, represents the entire

agreement of the parties relating to the subject matter hereto, and supersedes all previous discussions, representations, and understandings related to the subject matter of this Agreement.

3.2 Except as expressly set forth above, Member shall be bound by all of the terms and conditions of the Research Agreement.

IN WITNESS WHEREOF, the parties hereto agree to participate in this Agreement in accordance with the terms and conditions contained herein, and have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

FONDATION LEDUCQ:

MEMBER:

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

Name: David Tancredi

Title: Scientific Director

\_\_\_\_\_

Name:

## EXHIBIT 8

### FONDATION LEDUCQ: INVOICING INSTRUCTIONS

(May 2013)

Timely and accurate financial reporting is essential for the proper oversight and management of the network program. Each network must identify, hiring under the grant if necessary, a financial administrator whose responsibility it will be to manage the network budgets, communicate with FLQ about budgetary matters, provide regular financial reporting to FLQ, and otherwise oversee the spending and finances of the network. This person, the “Network Administrative Officer”, will serve as the direct interface between the network and the foundation administrative staff.

Networks should observe the following guidelines regarding budgets, invoices, and financial reporting:

1. Original invoices, signed by each institutional financial officer and accompanied by the Yearly Billing Chart, should be mailed through the office of the Grantee Coordinator, whose duty is to collect the invoices, to undersign each of them indicating approval, and then to remit them to the FLQ office. Invoices by e-mail are accepted.
2. FLQ must receive invoices on a quarterly basis.
3. Invoices for a given quarter should be submitted before the end of the subsequent quarter. Invoices for the October-December quarter must be received before the end of February to allow FLQ to close its accounts for the calendar year, in accordance with standard French accounting law and practice.
4. All invoices must clearly identify the institute of origin. They must be distinctly numbered and dated, include the grant number, and unambiguously identify FLQ as the recipient.
5. Quarterly invoices must reflect real expenses, not budgeted expenses.
6. Expenses are to be listed according to the following budgeted items:
  1. Salaries, with separate lines and subtotals for senior investigators, junior investigators and other salaried staff,
  2. Equipment in excess of USD 10,000 (invoice to be included),
  3. Computer equipment,
  4. Other equipment,
  5. Supplies,
  6. Animal-related costs,
  7. Subcontracted services (genotyping, etc.),
  8. Travel and accommodation
  9. Meeting expenses
  10. Communication
  11. Network administrative officer salary,
  12. Other expenses,

13. Indirect costs (limited to 10%)

7. The attached “billing chart template” (Exhibit 11) should be properly completed and joined to each set of quarterly invoices. One chart should be used for each fiscal/calendar year under the Agreement. The yearly budget is the original yearly budget corrected, whenever necessary, to take into account the under- or over- expenses of the previous years. (Previously non spent yearly budgets can be added to the on-going yearly budget - unless otherwise decided by the Foundation - during the five year period of the Research Agreement). Any significant change, i.e., one involving greater than 20% of network budget on a yearly basis, requires prior foundation approval. Investigators must be copied on the budgetary submissions to the foundation, in order that the foundation be assured that they are aware of their expenses.
8. Upon receipt of properly executed invoices, FLQ will reimburse directly each institution whose expenses are indicated on the invoice. In order to limit the foundation’s financial expenses, the financial office will not pay invoices that total less than \$1,500, but will roll over the amount to the next quarter.
9. Payments by FLQ are made by wire transfer. Invoices should provide detailed and up-to-date wiring instructions, including the account holder and number and IBAN, SWIFT/BIC, transit codes or Fed Fund eligible ABA (not ACH payment ABA), as applicable. Please report any changes in bank information to FLQ on a timely basis.
10. Where items are subject to tax, the percentage tax rate must be indicated. As a not-for-profit charitable organization, recognized of public interest (RUP) by the government of France, FLQ is exempt from the value added tax (VAT). European member institutions should not pay VAT on FLQ network program expenses, nor should such tax be imputed to the FLQ grant as a whole.

## Exhibit 9

### FONDATION LEDUCQ

#### Policy on Objectivity in Research by Grant Applicants and Grantees

##### ARTICLE 1: **PURPOSE**

1.1 The purpose of this Policy is to promote objectivity in research by establishing standards intended to ensure that the design, conduct, or reporting of research funded under FLQ grants will not be biased by any conflicting financial interest or relationship of an Investigator.

##### Article 2: **APPLICABILITY**

2.1 Subject to Section 4.4 of the Agreement, this Policy is applicable to each Institution (including Grantee Institutions and Member Institutions as defined in a Research Agreement), that applies to FLQ for grants for research and, through the implementation of this Policy by each Institution, to each Investigator at that Institution.

2.2 In the rare instances where an individual Investigator applies to FLQ directly for grants, the FLQ will request from Investigators any declarations of relevant significant financial interest, fiduciary relationship, and executive position as defined under sections 3.5, 3.6, and 3.7 and by applying this Policy for Objectivity in Research by Grant Applicants and Grantees, will undertake to manage conflicts of interest, making case-by-case determinations on the steps to be taken by such Investigator to ensure that the design, conduct, or reporting of research will not be biased by any conflicting financial interest of such Investigator.

##### Article 3: **DEFINITIONS**

3.1 Institution means any public or private entity or organization excluding a governmental agency or body.

3.2 FLQ means Fondation Leducq, a French charitable foundation having its administrative offices in Paris, France.

3.3 Investigators mean the individual Coordinators and Members as defined in a Research Agreement who are responsible for the design, conduct, or reporting of research funded by FLQ, or proposed for such funding. For purposes of the requirements of this Policy relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

3.4 Research Agreement means an agreement between FLQ, on the one hand, and Investigators and their respective Institutions on the other hand, pursuant to which FLQ provides funding for research in cardiovascular and neurovascular disease.

3.5 Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity

interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents and royalties from such rights). The term does not include:

3.5.1 Salary, royalties, or other remuneration from an Investigator's Institution;

3.5.2 Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

3.5.3 Income from service on advisory committees or review panels for public or nonprofit entities;

3.5.4 An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$15,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

3.5.5 Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$15,000.

3.6 Fiduciary Relationship means any position with a business, whether or not for-profit, which subjects an Investigator to a fiduciary duty to such business, including but not limited to, service in an Executive Position or as a member of the Board of Directors or other governing body of such business.

3.7 Executive Position means any position which includes fiduciary and other responsibilities for a material segment of the operation or management of a business. It specifically includes positions with the titles of "Scientific Director" and "Medical Director."

#### **Article 4: INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS**

Each Institution must:

4.1 Maintain an appropriate written, enforced policy on conflict of interest that complies with this Policy and inform each Investigator of this Policy and the Investigator's reporting responsibilities. If the Institution carries out the FLQ-funded research through others, the Institution must take steps to ensure that Investigators working for such entities comply with this Policy.

4.2 Designate an Institutional official(s) to obtain and review financial disclosure statements from each Investigator who is planning to participate in FLQ-funded research.

4.3 (1) Require that by the time an application is submitted to FLQ each Investigator who is planning to participate in the FLQ-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests and Fiduciary Relationships (and those of his/her spouse and dependent children), and Executive Positions:



(a) That would reasonably appear to be affected by the research for which FLQ funding is sought; and

(b) In entities whose financial interests would reasonably appear to be affected by the research.

(2) All such disclosures must be updated during the period commencing with the initial grant application and ending with the conclusion of FLQ support under the grant. Such updates shall be made, at a minimum, on an annual basis but shall be made sooner as new reportable Significant Financial Interests, Fiduciary Relationships, or Executive Positions are obtained.

4.4 Provide guidelines consistent with this Policy for the designated official(s) to identify conflicting interests and take such actions as are necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

4.5 Maintain records of all disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final report to FLQ.

4.6 Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

4.7 Certify, in each application for funding to which this Policy applies, that:

4.7.1 There is in effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from FLQ,

4.7.2 Prior to the Institution's expenditure of any funds under the award, the Institution will report to FLQ the existence of any conflicting interest found by the Institution and assure FLQ that the interest has been managed, reduced or eliminated in accordance with this Policy.

4.7.3 For any interest that the Institution identifies as conflicting subsequent to the Institution's initial report, a new report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification;

## Article 5: **MANAGEMENT OF CONFLICTING INTERESTS**

The designated official(s) must: Review all financial and fiduciary disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest or a Fiduciary Relationship or an Executive Position could directly and significantly affect the design, conduct, or reporting of FLQ-funded research. Such actions may include, without

limitation: public disclosure of the conflict; independent monitoring of research; disqualification from participation; or divestiture of Significant Financial Interests or Fiduciary Relationships.

Article 6: **REMEDIES**

6.1 If the Institution determines that the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of FLQ-funded research, the Institution must promptly notify FLQ of the corrective action taken or to be taken. FLQ will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action.

6.2 FLQ may at any time require the submission of, or review on site of, all records pertinent to compliance with this Policy. To the extent permitted by law, FLQ will maintain the confidentiality of all records of financial or fiduciary interests. On the basis of such review and/or other information, FLQ may decide that a particular conflict of interest will bias the objectivity of the FLQ-funded research to such an extent that further corrective action is needed. FLQ may determine that suspension of funding is necessary until the matter is resolved.

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