

## **GENERAL TERMS & CONDITIONS APPLICABLE TO PFIC NETWORK, INC. GRANTS**

The mission of PFIC Network, Inc. (the “Network”) is to improve the lives of patients and families, treatment options, slow disease progression, and ultimately find a cure for Progressive Familial Intrahepatic Cholestasis (“PFIC”) diseases. In accordance with that mission, the Network awards grants to certain researchers and/or research institutions based on the Network’s criteria. In addition to any criteria set forth in an applicable grant application or proposal (including but not limited to the specific terms and conditions applicable to each such grant), as set forth in the Notice of Award, these General Terms & Conditions (these “Terms”) apply to all of the Network’s grants.

Recipients of grants (“Grantees”) agree to these Terms as a condition of the acceptance and receipt of a grant award. Grantees; Researchers (as defined below); and all employees, representatives, contractors, and affiliates thereof are bound by, and must comply with, these Terms throughout the duration of the period of performance and at all times thereafter. The Network reserves the right to revise and update these Terms from time to time in its sole discretion.

### **I. AWARD OF GRANTS**

#### **Execution of Documents**

Any and all documents (including but not limited to agreements, applications, awards, and terms and conditions) associated with an award of grant may be executed, as applicable, in any number of counterparts, including counterparts received electronically as signed confirmed facsimiles or via email, and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement.

#### **Award Payments**

The Network will issue award payments for any grant as provided in the Notice of Award for such grant. The Network reserves the right to require additional documentation from any Grantee prior to issuance of any award payment if, in its reasonable discretion, such documentation is necessary to further the purposes of the award. Full funding of any Network grant is contingent upon the timely receipt of satisfactory and complete progress reports as provided in the applicable Notice of Award. Continued funding, where applicable, is contingent upon the Network having sufficient working capital (as determined by the Network in its sole discretion) to continue to fund the applicable grant installment(s). The Network may withhold any payment if any required documentation (including any additional documents requested pursuant to this paragraph) is not timely provided by Grantee.

#### **Publications/Acknowledgement**

Publications, abstracts, manuscripts, and/or presentations at scientific conferences and/or meetings based on, or resulting from, any study or research performed during the period of performance must acknowledge the Network using the following language: “Funded in part by a grant from the PFIC Network.” The Network reserves the right to modify this acknowledgement at any time in its sole discretion. The Network shall notify the Grantee in writing in the event that a modification to the acknowledgement is required.

### **Renewal for Additional Years of Multi-Year Awards**

The renewal of the second year of any multi-year award is contingent upon the receipt of all applicable documentation, including but not limited to any budgets, progress reports, or other documents as set forth in the applicable Notice of Award and/or as requested by the Network, and that all such documentation be timely, satisfactory, and complete. The Progress Reports section of these Terms sets forth the reporting requirements. All progress report shall be reviewed by the Network to ensure that sufficient work and progress has been made on the grant to support continued funding the project. If the Network determines, in its sole discretion, that an insufficient amount of progress has been made on a project, the Network reserves the right to discontinue financial support for such grant. In addition, if a project requires Institutional Review Board (“IRB”) approval, Grantee must submit all applicable IRB approvals and renewal letters to the Network in order to continue funding for the project.

### **Carryover of Funds**

A carry over of funds is defined as the use of funds from a one period of performance to a subsequent period of performance without an extension to the grant’s originally approved end date. Requests for a carryover of funds must be submitted in writing to the Network no less than thirty (30) days and no more than sixty (60) days prior to the award’s annual anniversary or official termination date, as applicable. *Prior written authorization must be obtained from the Network before a carryover of funds can take effect.* The request must: (a) provide a clear justification for the carryover of funds; (b) specify the precise amount of funds to be carried over; (c) state all budget line items affected by the carryover (including but not limited to details of changes in supplies or equipment portions of the budget); and (d) individually itemize all affected items.

### **No Cost Extension**

A no-cost extension is defined as an extension of the termination date of the grant period from the end date of the original award which is not associated with a request for additional funding. A no-cost extension may be requested to allow for the completion of the project as originally described. A no-cost extension may not be requested to complete an experimental plan different from the one approved in the original grant, nor can a no-cost extension be used for the purpose of spending unused funds. Requests for no-cost extensions must be submitted in writing to the Network no less than thirty (30) days and no more than sixty (60) days prior to the award’s annual anniversary or official termination date, as applicable. *Prior written authorization must be obtained from the Network before a no cost extension can take effect.* All such requests must provide a clear justification of the need of the no-cost extension.

### **Grant Extension Requesting Additional Funds**

The Network reserves the right to allow requests by a Grantee for additional funds to continue promising Network-funded projects beyond the period of performance set forth the original award. In the event the Network decides, in its sole discretion, to allow such a requests, it must follow the Network’s then-applicable procedures for submission of new grant requests.

### **Authorized Award Holders**

Network grants are awarded to particular, designated individuals holding full-time positions at established academic, non-profit, and/or government institutions. Grant funds are transferred to the institution employing such individuals. Some institutions assess overhead or other indirect costs with respect to grants. Network funds may not be used by any institutions to pay any such indirect

costs under any circumstances. The restriction on the use of Network funds set forth in the preceding sentence is a material condition of all awards.

### **Non-US Grant Awards**

The Network may, from time to time, award a grant to an applicant based outside the United States of America. In the event that the Network decides to open a grant application to non-US applicants, such applicants may be required to obtain clearance from the United States Internal Revenue Service and/or provide such other registrations, approvals, and/or other documentation (all at the applicant's expense) as the Network, in its sole and exclusive discretion, may determine with respect to such grant. The fact that the Network may, from time to time, require a non-US applicant to submit certain approvals or other documentation with respect to an award shall not limit the Network from requiring any other approvals or other documentation it deems necessary in relation to any other award, nor shall it limit the Network from requesting additional approvals or other documentation from an already-approved Grantee if, in its sole and exclusive discretion, the Network deems it necessary.

### **Change of Researcher/Institution**

No Network award of grant may be transferred, assigned, or otherwise conveyed to any person or entity other than the person or entity to whom it was originally awarded (the "Researcher") without the prior written approval of the Network. The Researcher shall be considered the principal investigator unless otherwise expressly stated in the Notice of Award. A request to transfer a grant to another person or entity must be made in writing to the Network. The Network, in its sole and exclusive discretion, may approve such transfer request or require a competitive application process for renewal of the grant. If the Network approves a change to the institutional entity with respect to any award, any funds that have been unexpended at the former institution must be returned to the Network within thirty (30) days after the transfer takes effect.

### **Change of Key Individuals**

Requests to any change key personnel (including but not limited to researchers, mentors, or other principals) with respect to any Network grant must be made by in writing to the Network. Such requests must include a copy of the new key personnel's Biosketch and Other Support page. *The Network's prior written approval must be obtained before the requested new key personnel begins work on the project.*

### **Change of Individuals Who Are Not Key Individuals**

Any change made to individuals who are not named as key personnel in the grant application may be made by the Grantee at any time during the performance of the grant. The Network does not require prior written approval for such changes. Grantee is nevertheless required to promptly notify the Network in writing at the time such changes are made.

### **Financial Conflicts of Interest**

All persons and entities awarded grants by the Network shall adhere to the Department of Health and Human Service's Regulation on Responsibility of Applicants for Promoting Objectivity in Research for which Health Service funding is sought (42 C.F.R. Part 50, Subpart F).

### **Early Completion of Grants**

The Network shall only pay for work performed. Should a Grantee complete a project ahead of the scheduled end date of the period of performance, the Network shall only pay for the time spent completing the work. Any remaining funds shall be returned to the Network within thirty

(30) days of the completion of such work.

### **Grant Ending Notification**

A grant is considered complete once all documentation required hereunder has been received and all payments set forth in the applicable Notice of Award have been made. The Network shall notify the Grantee in writing that the grant has been completed and each party has successfully met its obligations and requirements.

## **II. REPORTING REQUIREMENTS**

The Network may disclose to third parties, or otherwise make public, any payment or other transfer of value made to any Grantee as required by applicable law, regulation, or contractual obligation.

### **Progress Reports**

Any final progress report required by the Notice of Award must be timely made to the Network in accordance with the terms of the applicable Notice of Award.

The reporting requirements for final progress reports are as follows: Lay Summary, Activity Summary, Impact, Budget Summary, Publications, Presentations, Patents, Grants, Clinical Trials, Educational Materials, Public Policy, Data Sharing Plan, Other Pertinent Study Generated Findings, and Continuation of Academic Career.

For awards extending beyond one (1) calendar year, the Network may require an annual progress report at the end of each calendar year of the grant. Such annual reports must include the following: Activity Summary, Budget Summary, Presentation of Results and Ongoing Plans Involving Study Generated Data. In addition, Grantees are required to provide an updated Other Support Page to the Network with each annual progress report for the grant.

A progress report will be deemed unsatisfactory if any of the mutually agreed upon reporting requirements is unfulfilled. The due dates shall be reflected in the Notice of Award. Any future payments due on the project shall be withheld until all required documents, including any progress reports, are received, reviewed and approved by the Network. The Network may withhold any payments still to be made under any award if any required documentation, including but not limited to any required abstract or paper required to be included in a final progress report. All progress reports must be submitted to the Network electronically.

### **Budget Summary Portion of the Progress Report**

At the conclusion of the first year of the award period and/or at the end of the award period, the Network requires a complete budget summary encompassing the entire award period. The Budget Summary must provide a detailed listing of actual expenditures itemized and organized in such a way as to allow ready comparison with the projected expenditures submitted with the grant application and approved by the Network. If a Grantee desires to reallocate funds, please see the Change in Budget section of these Terms. Any funds used for unauthorized expenditures or unexpended funds must be returned to the Network thirty (30) days after the award has terminated.

### **Change of Budget**

The original budget refers to the description of funds awarded to the Grantee in the original

application.

A change to the original budget representing an amount less than 10% of the total amount of the annual budget may be made at the discretion of the Grantee and does not require prior approval by the Network. Any cumulative change to the grant's budget representing an amount greater than 10% of the total amount of the annual budget requires prior written approval by the Network. Budget change requests greater than 10% of the entire annual budget must be submitted to the Network in writing. When requesting a change to the budget, the Grantee must indicate the US dollar value of the requested change (using the current bank exchange rate, as applicable). The budget line from which the funds are to be removed and the budget line to which the funds are to be transferred must also be clearly indicated. Further, a written explanation of the requested budget change must be included in the request. In the case of a change to the supply or equipment portion of the budget, all items that will be affected by the budget change must be individually itemized. Any funds used for any unauthorized expenditures, in excess of 10% of the entire budget without prior written approval of the Network must be returned to the Network within thirty (30) days of the termination of the applicable period of performance. Any change to the budget must be reflected in the budget summary that is submitted with the grant's annual and/or final progress report.

### **III. TERMS AND CONDITIONS FOR USE OF NETWORK RESEARCH FUNDS**

#### **A. Permitted Uses of Funds**

##### **Salary Support**

Salary support shall be provided for the Grantee or other individuals working on a project funded by a Network grant only in an amount equivalent to the effort of such individual on the project funded by such grant. Salary support in excess of the effort provided by an individual will not be approved. Salary support is calculated by multiplying the individual's institutional base salary by the percent of effort on the project. The maximum effort that can be listed on the budget page for an individual is 100%. If the salary support requested by a key individual is less than the percent effort to be provided, the source of the additional salary support for this individual must be disclosed to the Network. Any deviation from these policies may result in a request for clarification or modification of the original budget by the Network prior to payment of any applicable portion of an award. Such adjustments related the salary support will be made at the time of award.

##### **Direct Expenses**

The Network will only pay for those direct costs, including fringe benefits, associated with execution of a grant award. An applicant may not request funds to include any items that are treated by the applicant organization as indirect costs.

#### **B. Prohibited Uses of Funds**

##### **Indirect Costs**

No grant funds may be used to pay for overhead and/or indirect costs.

**Equipment Repair & Service Contracts**

No grant funds may be used to pay for the repair or maintenance of, or for service contracts on, Grantee's equipment.

**Project Support Expenditures**

No grant funds may be for the purchase of furniture, construction or renovation of facilities, payment of honoraria or membership dues, travel to non-grant related meetings, purchase of textbooks or periodicals, or payment for secretarial support.

**Illegal or Unethical Use**

Network funds may not be used, directly or indirectly, for any purpose which is prohibited by law; to offer gifts or other things of value in order to improperly influence any other person or entity; or for any lobbying effort directed to any elected official or attempt to influence the outcome of an election. Grantee must comply with all applicable national, state, local, or other lobbying, gift, and ethics rules.

**C. Restricted Uses****Equipment and Supply Purchases**

Upon conclusion of the award, equipment and supplies purchased with funds from the award, and in accordance with the original grant application, become the property of the institution at which the work was performed unless the Network provides prior written approval of an alternative disposition of such assets.

**D. Investment of Funds**

Should the Notice of Award provide for investment of grant funds, Grantee must invest Network-provided funds in highly liquid investments with the primary objective of preservation of principal (eg., an interest-bearing account or a registered money market mutual fund) so that the grant funds are available for the project for which the grant was awarded. Together with any progress or final reports required under these Terms, Grantee must report the amount of any currency conversion gains (or losses) and the amount of any interest or other income generated by the Network funds (collectively, "Income"). Any Income must be used for said project.

#### **IV. PATENTS AND INTELLECTUAL PROPERTY RIGHTS AND OWNERSHIP**

Inventions and discoveries resulting from or in connection with research performed during the term of a Network grant will be governed by the Network's patent and intellectual property policy, as described below.

**A.** All inventions or intellectual property made with the support, in whole or in part, by awards from the Network must be reported in writing, at the earliest practical time, to the Network. Grantee agrees to notify the Network immediately of the decision to apply for letters of patent or other legal protection for intellectual property, and to consider seriously and in good faith any comments or objections the Network may have concerning such applications. The Network shall keep all information confidential in accordance with its established practices and charitable mission. All patenting expenses shall be borne by the Grantee.

**B.** All rights to patentable discoveries conceived and reduced to practice by Grantee in the performance of a Network-supported project ("Invention") shall belong to Grantee and shall be

disposed of in accordance with Grantee's written policies, a copy of which will be provided to the Network prior to the disbursement of any Grant funds. In the event of a conflict between the Grantee's policies and the terms hereof, the parties agree to negotiate in good faith a resolution to such conflict. In the event Grantee does not have a written policy covering such issues, the Network's policies shall govern. Grantee shall promptly inform the Network of any and all subsequent patent protection and commercialization activities related to or arising from the Invention. Grantee shall include diligence provisions in all license agreements for the Invention for the timely commercial development and early marketing of Invention in accordance with Paragraph E of this Section.

**C.** Distribution of income derived from an Invention or other intellectual property, which might include equity disposition, shall provide that the Network will participate in income derived from any such Invention or intellectual property to the extent and at a rate of remuneration determined by mutual agreement, based on a good faith negotiation, between the Grantee and the Network no later than one (1) month after the first receipt of income. Such agreement shall be guided by the principle that the Network's proportional share in such income shall be reasonably related to the Network's proportion of support for such Invention or intellectual property.

**D.** No patent, patent application, or other type of protection shall be abandoned without first notifying the Network in writing. At such time, the Grantee shall provide the Network with the opportunity to proceed with the application in the Network's name and to take title to the Invention or other intellectual property.

**E.** The Grantee agrees that if it licenses any Invention or other intellectual property subject to this Section, it shall obligate the licensee as follows:

- (1) The licensee agrees to exert its best efforts to commercialize, or cause to be commercialized, such Invention or intellectual property as rapidly as practicable, consistent with sound and reasonable business practices and judgment.
- (2) In the event that the licensee has failed to commercialize the invention or intellectual property within a number of years determined to be reasonable for such Invention or intellectual property, Grantee, upon conferring with the Network, shall have the right to convert an exclusive license to a non-exclusive license, or to terminate a non-exclusive license.
- (3) If the licensee or Grantee has any ongoing and active research, development, manufacturing, marketing, or licensing program(s) appropriately directed toward the production and sale of such Invention or intellectual property, this shall be deemed sufficient evidence that the licensee or Grantee institution has commercialized said Invention or intellectual property.

**F.** The Network reserves the right to public acknowledgement for Inventions or other intellectual property arising from or relating to research conducted with the Network's support. Notwithstanding the foregoing, the Network's name and logo may not be used in association with any Invention or other intellectual property without the Network's prior written approval.

**G.** The Network shall have access to, and use of, Inventions or services and/or products protected as intellectual property without payment of royalties or fees for use by the Network in accordance with its established practices and charitable mission. For the avoidance of doubt, this subsection G shall be construed as broadly as possible to provide the Network with a perpetual, worldwide, royalty-free, non-exclusive license to any invention or other intellectual property (and any products or services derived from or related to such inventions or intellectual property) subject to this Section in addition to any other rights or interests it may have in such inventions or intellectual property (whether pursuant to these Terms, the terms of an award, or by operation of law).

**H.** All data and/or biological samples obtained and/or created as part of an award shall belong to the Network unless otherwise agreed in writing by the Network. The Grantee agrees to work cooperatively with the Network to transfer such data or samples to the applicable Network registry.

## **V. TERMINATION**

### **Termination at Will**

Both Parties reserve the right to terminate this Agreement for any reason upon sixty (60) days prior written notice to the other Party. In the event of such termination of an award, the Network shall immediately cease incurring any additional costs in connection with such award. The Network's sole obligation to the Grantee shall be limited to payment for grant-related activities performed by Grantee prior to the effective date of such termination. Any funding provided by the Network prior to such termination and not used by Grantee prior to receiving notice of such termination shall be returned to the Network within thirty (30) days of the effective date of termination. Grantee shall be obligated provide a progress report on the work performed prior to the effective date of termination regardless which Party initiated such termination.

### **Termination For Cause**

An award may be terminated by the Network immediately for cause at any time in the event that the Network is not reasonably satisfied with the progress of the project and/or if Grantee engages in any of the following: fraud; embezzlement; theft; excessive use of alcohol or illegal drugs interfering with performance of Grantee's duties or otherwise reflecting negatively upon the Network; disclosure of the Network's confidential information; moral turpitude; commission of any felony or of any crime involving the Network or the award; habitual absenteeism or tardiness; gross negligence or a pattern of negligence in the performance of any of Grantee's material duties; gross incompetence or a pattern of incompetence in the performance of Grantee's material duties; failure or refusal to perform any of Grantee's material duties including, without limitation, any of the material terms and provisions of these terms (including but not limited to reporting requirements and limitations on use of award funds); or any intentional or willful act or omission by Grantee resulting in material injury to the property, personnel, or operations of the Network.

## **VI. MISCELLANEOUS**

### **Correspondence/Notices**

The Network directs all correspondence to the Administrative Official and/or Researcher named on the face of the grant application submitted to the Network. As such, it is the responsibility of

such Administrative Official and/or Researcher to ensure that all applicable grant personnel, and all other appropriate personnel, are copied on all Network and/or Administrative Official and/or Researcher correspondence.

Any notice or other communication under this agreement shall be in writing and shall be deemed to have been given if delivered personally or by U.S. first class, registered or certified mail, postage prepaid, addressed to the recipient at such address as provided by such Party hereunder. Either Party may designate another address in writing (or by such other method approved by the Network, including but not limited to electronic mail) from time to time. The Network may from time to time designate a specific contact person to whom Grantee shall direct specific notices, reports, or other documents or correspondence is to be sent.

### **Release of Information**

The Network may disseminate information about the award in its reasonable discretion, including but not limited to posting information regarding the award on the Network's website (www.pfic.org). The names of the Researcher, institution, as well as the grant's title, and a description of the project may be included on the Network's website as a part of the award announcement. The Administrative Official and/or the Researcher may be contacted by the Network for additional information or authorizations.

### **Liability and Indemnification**

The Grantee agrees to indemnify and hold the Network harmless from any and all liabilities, losses, claims, costs, damages, causes of action, judgments or settlements arising therefrom, including reasonable attorney's fees, arising out of its breach of any of its representations or obligations set forth herein or in any application or other documents, its use of any informed consent or other disclosure document that fails to adequately address all risks or disclosures that should be set forth in such document, and from any and all research or investigations performed by the Grantee, whether or not such research or investigation was supported by Network funds.

The Network agrees to indemnify and hold the Grantee harmless from any and all liabilities, losses, claims, costs, damages, causes of action, judgments or settlements arising therefrom, including reasonable attorney's fees, arising from its failure to provide the grant funds as agreed after written notice and expiration of a ten (10) day period to cure. The Network shall not be obligated to indemnify or hold harmless the Grantee or any party through any provision or section of any agreement that the Network has not executed. In the event of a conflict between any such document or agreement and this agreement, the terms of this agreement shall control.

### **Force Majeure**

Neither Party shall be held liable or responsible to each other, nor be deemed to have defaulted under or be in breach of this agreement, for failure or delay in fulfilling or performing any term of this agreement when such failure or delay is caused by, or results from, causes beyond the reasonable control of the affected Party ("FM Party"), including but not limited to fire; floods; war, insurrection, or riot; failure or termination electrical power service or communications systems or networks; inability to procure materials that could not have been reasonably anticipated and avoided by the FM Party; strikes, lockouts, or other labor disturbances; acts of God; or acts, omissions, or delays in acting by any governmental authority or the other Party; provided, however, that the FM Party shall use commercially reasonable efforts to avoid, mitigate, or remove such causes of nonperformance, and shall continue performance hereunder with reasonable dispatch whenever such causes are removed.

**Health Insurance Portability and Accountability Act Compliancy**

Where applicable, the Grantee will comply with the Health Insurance Portability and Accountability Act (HIPAA) as well as all regulations promulgated thereunder. If requested by the Network, the Grantee must provide executed copies of all agreements demonstrating complicity with all applicable HIPAA regulations, if any.

**Equal Employment Opportunity**

The Network's grants shall only be awarded to individuals working in institutions identified as Equal Opportunity Employers.

**Employment Status**

At the time of the application's submission and throughout the award, the Grantee must be employed by the applicant organization named on the face of the grant application. Notwithstanding any other provision of these Terms or any Notice of Award, nothing in these Terms, any Notice of Award, or any other document or communication between the Parties shall be construed as creating an employment relationship between the Network and any Grantee, or affiliate of any Grantee, unless such document expressly so states.

The Grantee institution is responsible for all acts and omissions of any of its trustees, directors, officers, employees, subgrantees, subcontractors, contingent workers, agents, and affiliates assisting with the award project and for ensuring their compliance with these terms.

**Compliance**

Grantee shall comply with all applicable laws, regulations, and rules and shall not infringe upon, misappropriate, or otherwise violate the intellectual property, privacy, or publicity rights of any third party.

**Governing Law**

These Terms and any Notice of Award shall be governed by, and construed and enforced in accordance with, the laws of the Commonwealth of Kentucky. The Courts of the Commonwealth of Kentucky, County of Jefferson, shall have jurisdiction over any dispute arising under this agreement. The Parties hereby consent to personal jurisdiction in the courts of the Commonwealth of Kentucky, County of Jefferson, for purposes of any such dispute and waive any objection as to venue.

**Severability**

If one or more provisions of these Terms or any Notice of Award are held to be unenforceable under applicable law, the Parties agree to renegotiate such provision in good faith. In the event that the Parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (a) such provision shall be excluded from this agreement; (b) the balance of the agreement shall be interpreted as if such provision were so excluded; and (c) the balance of the agreement shall be enforceable in accordance with its terms.