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## **3-Year (2009-12)**

# **FOLLICULAR LYMPHOMA CORRELATIVE CLINICAL STUDIES AWARD**

## **POLICY STATEMENT & TERMS AND CONDITIONS**

### **Policy Statement**

The Lymphoma Research Foundation (LRF) was created to provide funding for lymphoma research and provide information and support for those patients and their families whose lives have been affected by lymphoma.

To ensure that the money LRF raises is directed toward the leading edge of lymphoma research, applications are reviewed by the LRF Scientific Advisory Board (SAB), a volunteer group of scientists distinguished in fields related to lymphoma research. They make their judgments based on the scientific merit of the project, the demonstrated ability of the researcher, and the suitability of the Sponsoring Institution. The members of the SAB review the applications independently, and make their recommendation to the LRF Board of Directors (Board).

The Board of Directors studies the recommendations of the SAB. Their aim is to select those recommended applications that seem most likely to help the LRF achieve its overall research goals. LRF funds research projects submitted by individuals associated with accredited academic institutions, the Joint Commission of Accreditation of Healthcare Organizations (JCAHO), and accredited research hospitals and/or other research organizations that have national and international reputations for excellence, on the terms and conditions set forth herein.

### **Terms and Conditions**

The term of each LRF Follicular Lymphoma (FL) Research Grant is set according to the budget and timeline approved by the SAB. The award is subject to termination by LRF in the event that LRF does not receive a progress report from the LRF FL Grantee in accordance with the requirements set forth in Section 9 ("Progress Reports") and an Institutional financial report in accordance with the requirements set forth in Section 10 ("Accounting Reports") below. In the event of any such termination, the Sponsoring Institution must return any remaining funds.

The LRF FL Grant provides support as stipulated in the budget approved by the SAB.

Payments from LRF FL Grants shall be made to the comptroller or to the designated financial officer of the Sponsoring Institution on a quarterly basis. The Sponsoring Institution shall disburse the funds to the LRF FL Grantee during the term of the grant in accordance with the budget approved by LRF. Unless otherwise agreed, the first quarterly payment shall be paid during the 3<sup>rd</sup> quarter of 2009.

The LRF FL Grantee must be affiliated with the Sponsoring Institution at the time of funding and at all times during the term of the LRF FL Grant. (See Section 6 for Transfers, if necessary). Funds shall be paid to and administered by the Sponsoring Institution.

The Sponsoring Institution and the LRF FL Grantee shall each, jointly and severally, pay at their own cost, all taxes and impositions in connection with the LRF FL Grant, including, but not limited to State and Federal unemployment taxes, social security taxes, income taxes, and sales taxes.

The LRF FL Grant does not create an employer-employee relationship between the LRF FL Grantee and LRF. The LRF FL Grantee and the Sponsoring Institution may not bind LRF to any contract or any obligation without the express written consent of LRF. LRF does not assume any legal responsibility or obligation for the conduct or acts of the LRF FL Grantee or the Sponsoring Institution.

**The following sections provide specific information on other Terms and Conditions that must be met:**

### ***1. Indemnity***

The Sponsoring Institution and the LRF FL Grantee shall, jointly and severally, indemnify LRF and hold it harmless against any and all liabilities, claims, and demands that relate to the research of the LRF FL Grantee or the LRF FL Grant, including, but not limited to those for personal injury, property damage, or malpractice.

### ***2. Funding***

The LRF FL Grant shall be used solely for the purposes specified in the application submitted to LRF. The LRF FL Grantee and Sponsoring Institution shall adhere strictly to the funding and budget guidelines approved by LRF. If the LRF FL Grant is not activated for any reason within 6 months of the grant's commencement date, that grant may be terminated by LRF.

### ***3. Notification of Funding***

Applicants chosen as LRF FL Grantees will be notified by telephone or e-mail and a contractual agreement forwarded to them no later than March 2009. Quarterly payments will be made commencing on in the third quarter of 2009 or as soon thereafter as the signed contractual agreement is received by LRF.

#### **4. Acknowledgments**

The LRF FL Grantee and the Sponsoring Institution agree that the title “Lymphoma Research Foundation Follicular Lymphoma Grantee” shall be used in all publications, research talks, and poster presentations during the period of the LRF FL Grant. Identification with LRF shall be made in any news or press releases regarding the LRF FL Grantee or regarding the LRF FL Grantee’s research project by any press organization, Department of Public Relations, or its equivalent at the Sponsoring Institution. In addition, the LRF FL Grantee agrees to acknowledge LRF in all future publications, research talks, and poster presentations that result from the funded research project and to forward copies of such publications to LRF. Notwithstanding the foregoing, all uses of the LRF name, trademarks and logos (LRF Marks) shall be subject to LRF prior approval and LRF may revoke the right to use the LRF Marks at any time.

The LRF FL Grantee and the Sponsoring Institution each authorize LRF to use their names and likenesses and any combination thereof in any of LRF’s press releases, brochures, films, videotapes, and any other form of media used to publicize LRF and/or for educational purposes.

#### **5. Integrity of the Research**

It is the goal of LRF to increase the cure rates for Follicular Lymphoma. The highest scientific standards in the conduct of the research supported by any LRF FL Grant must be maintained by the LRF FL Grantee and the Sponsoring Institution. LRF FL Grantees agree to abide by all applicable Federal standards defining integrity and misconduct in research.<sup>1</sup>

#### **6. Transfers and Changes in Research Plan**

If the LRF FL Grantee desires to transfer to another Sponsoring Institution and/or significantly modify the research plan while the LRF FL Grant is in effect, continuation of funding is subject to the prior written authorization of the LRF SAB and Board of Directors, in their sole discretion. The LRF FL Grantee shall immediately submit to the SAB a written request for research plan modification only. For transfer to another Sponsoring Institution (with or without modification to research plan), the LRF FL Grantee shall submit a request to the SAB not later than the date on which the new Sponsoring Institution has agreed to the transfer or 60 days prior to the anticipated transfer, whichever date is earlier. However, it is recommended that Grantees confidentially communicate possible transfer and/or research plan modification informally to LRF in advance to facilitate acquiring Board action when needed and to obtain advice on the approval process.

In addition to the written request, the LRF FL Grantee must submit a report outlining the advantages of the transfer and the effect of the transfer on the progress of the research project involved. If, included with the transfer, the LRF FL Grantee proposes modification of the research project, the report shall also contain a complete description of the research project that

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<sup>1</sup> The US Public Health Service defines scientific misconduct as “fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research” (42 CFR Part 50, Subpart A). <http://grants.nih.gov/grants/policy/emprograms/overview/integsci.htm>

highlights proposed modifications. A budget outline from the administrative department of the new Sponsoring Institution shall also be provided.

Only one transfer per year may be requested for each LRF FL Grantee. A final accounting of disbursements of the LRF FL Grant funds by the original Sponsoring Institution through the transfer date shall be submitted by the original Sponsoring Institution within 30 days of the transfer.

LRF reserves the absolute right to disapprove any transfer or any modification of a funded research project or both for any reason with or without cause.

### ***7. Reallocation, Carry-over, and Reinstatement of Funds***

Request for reallocation of LRF FL Grant funds and requests to carry over funds from the previous year must be made at least 30 days prior to the anticipated need and are subject to the prior written authorization of the SAB, in its sole discretion. Funds will not be reinstated after LRF has received written notice of the LRF FL Grantee's intent to terminate the research project.

### ***8. Leave of Absence***

Leave of absence may be granted for up to 1 year at the sole discretion of the SAB. Maternity leave may be granted for up to 6 months. A written request for a leave of absence shall be submitted to the SAB as soon as the need for a leave of absence is known, or at least 30 days in advance of the anticipated date of the commencement of the leave, whichever date is earlier. If the request for a leave of absence is granted, funding shall be suspended during the period of the leave of absence upon the commencement date of the leave. The LRF FL Grantee and the Sponsoring Institution must return any unused funds to LRF with an accounting within 30 days of the commencement date of the leave. The SAB may elect in its sole discretion to terminate the LRF FL Grant or to suspend it pending the LRF Grantee's return from the leave of absence.

In the event the LRF FL Grantee's research is interrupted due to an incapacitating physical or mental illness or death, the LRF FL Grant is terminated and the unused portion of the funds must be returned to LRF by the LRF FL Grantee (or legal representative) and the Sponsoring Institution with an accounting within 30 days of the date of termination. The LRF FL Grantee or the Sponsoring Institution (or legal representative) shall promptly inform the SAB of the incapacitation of the LRF FL Grantee. In the event of death of the LRF FL Grantee, the Sponsoring Institution (or legal representative) shall contact LRF.

### ***9. Progress Reports***

After the first year's funding, the LRF FL Grantee shall submit a typewritten summary documenting in reasonable detail his or her research progress. This report shall include a one-paragraph summary written for the general public and prepared in language easily understandable by readers of a daily newspaper. Brief and concise documentation of the research results that have impacted on the field of follicular lymphoma, as well as all publications concerning the work of the LRF FL Grantee, shall also be included in the report. If in the sole judgment of the SAB significant progress has not been made during any year of the grant, LRF reserves the right to cancel the grant.

The first year's progress report must be received by LRF no later than August 2010. Without limiting LRF's rights (as set forth above) to terminate the LRF FL Grant, in the event LRF does not receive the progress report in a timely manner, subsequent payments of the LRF FL Grant award will not be made. Progress reports for each subsequent year of multi-year grants will be due in August of each funded year.

At the expiration of the grant period, the LRF FL Grantee must write and submit a final report that summarizes the research conducted. This final report shall include a one-paragraph summary of the research project written in language easily understandable by readers of a daily newspaper. A bibliography of all patents and publications (including published abstracts, public talks, journal articles, book chapters, poster presentations, etc.) concerning the work of the LRF FL Grantee during the grant period must be included in the final report. Reprints of peer-reviewed publications and copies of patents must also be submitted. To present the research fully and clearly, it is recommended that all reports include figures, diagrams, and photographs, as needed. The final report must be received within 30 days of the conclusion of the grant.

As a recipient of an LRF Follicular Initiative grant you are required to participate in the FL annual progress-reporting workshop and to join the LRF's FL consortium.

The LRF FL Grantee agrees to be interviewed by LRF upon termination of the LRF FL Grant or at any time during the grant period to determine how funding provided by LRF influenced his or her career and how it may have contributed to finding a cure and/or treatments for lymphoma.

### ***10. Accounting Reports***

The comptroller or other financial officer of the Sponsoring Institution shall submit an accounting report of how the LRF FL Grant funds were expended during the grant period. The accounting report shall be submitted to the LRF within 60 days of the completion of each year of the LRF FL Grant. Any unexpended funds must be returned to LRF with the accounting report.

### ***11. Collaboration / Communication***

A goal of the grant is to promote collaboration and communication among researchers in order to synergize and stimulate progress in the field. Therefore, FL grantees will be encouraged to share non-confidential data, findings and concepts. FL Grantees should be prepared to deliver a presentation on (interim) findings once annually at a venue to be chosen by LRF. (More details will be provided at the appropriate time. Travel expenses will not be part of this Award but will be covered separately by LRF.) Furthermore, should a FL consortium, website or other method/medium for communication be formed in future, all FL grantees will be required to participate.

### ***12. Research Involving Vertebrate Animals, Human Subjects, or Biohazards***

Research projects involving human subjects and/or vertebrate animals must meet or exceed standards required for Federal Government funding. If the proposed research will involve the use of human or vertebrate animal subjects, a signed release from the appropriate committee of the Sponsoring Institution must be provided to demonstrate approval of the proposed research protocol(s) before grant funds are released. The following sections provide specific information.

## **12 (a) Vertebrate Animals**

The Applicant and Sponsoring Institution affirm that research involving animals shall conform with the current “Guide for the Care and Use of Laboratory Animals,” National Institute of Health (NIH) publication, Department of Health and Human Services (DHHS)/U.S. Public Health Service (PHS) standards, the current PHS policy on animal research, and the “Guiding Principles on the Care and Use of Animals,” approved by the Council of the American Physiological Society. Research involving animals must also comply with all Federal and State laws and regulations, and must include approval by an institutional Animal Review Committee if required. The Applicant shall include a statement that the Applicant and the Sponsoring Institution meet and adhere to these policies and will each continue to do so throughout the duration of the LRF FL Grant period.

### **Exempt Projects**

Those projects that do not involve the use of laboratory animals must indicate that fact by including a statement signed by the Applicant and Sponsoring Institution noting “The development of the research project at the present time does not involve the use of laboratory animals.”

### **Changes in Research Plan**

If research plans are changed and the use of vertebrate animals is anticipated, no research may be performed using animals until appropriate Sponsoring Institution committee(s) has approved and that approval has been reviewed by the SAB. Failure to notify LRF of the use of vertebrate animals in a LRF Grantee’s research may result in the termination of the LRF FL Grant.

**LRF assumes no responsibility or liability for the use or care of any animal used in a research project supported by a LRF FL Grant and the LRF Grantee and Sponsoring Institution shall each indemnify and hold LRF harmless from any damages or injuries resulting from the use and care of any animal used in any such research.**

## **12 (b) Human Subjects**

The Applicant and Sponsoring Institution affirm that investigations involving human subjects and materials proposed in the application and subsequently carried out have been endorsed by the Committee on Clinical Investigation or other appropriate designated body of the Sponsoring Institution. The LRF FL Grantee Sponsoring Institution further affirm that any research involving human subjects will conform ethically with the guidelines prescribed by the NIH, including the provision of suitable explanation to human subjects or their guardians concerning experimental design and all significant hazards so that they may be in a position to provide appropriate informed consent prior to the investigations. All applications shall include a statement indicating approval from the appropriate body at the Sponsoring Institution guaranteeing that ethical guidelines shall be met.

### **Exempt Projects**

Those projects that do not deal with human subjects shall include a statement signed by the Applicant and Sponsoring Institution noting “The development of the research project at the present time does not involve the use of human subjects or materials.”

### **Changes in Research Plan**

If research plans are changed and the use of human subjects or materials is anticipated, no research may be performed with human subjects or materials until appropriate Sponsoring Institution committee(s) have approved and that approval has been reviewed by the SAB. Failure to notify LRF of the use of human subjects or materials in a LRF Grantee’s research may result in the termination of the LRF FL Grant.

**LRF assumes no responsibility or liability for the authorized or unauthorized use of human subjects and materials in any research funded by any LRF FL Grant and the LRF FL Grantee and Sponsoring Institution shall each indemnify jointly and severally, hold LRF harmless from any damages or injuries resulting from the use of human subjects and materials.**

## **12 (c) Biohazards**

All Applicants shall include in the application a statement describing any potential biohazards and a description of the safeguards planned where such hazards to any life form, including human, animal, and plant, may be encountered. When applicable, the research protocol shall be reviewed and approved by the Sponsoring Institution’s Biohazards Committee and shall conform to NIH guidelines.

### **Exempt Projects**

Those projects that do not deal with biohazards shall include a statement signed by the Applicant and Sponsoring Institution noting “The development of the research project at the present time does not involve the use of regulated biohazards.”

### **Changes in Research Plan**

If research plans are changed and the involvement of regulated biohazards is anticipated, no research may be performed that involves such hazards until the appropriate Sponsoring Institution regulatory committee(s) have approved and that approval has been reviewed by the LRF SAB. Failure to notify LRF of the involvement of regulated biohazards in a LRF Grantee’s research may result in the termination of the LRF FL Grant.

**LRF assumes no responsibility or liability for any such biohazards or the failure of any safeguard and the LRF Grantee, Sponsor, and Sponsoring Institution shall each indemnify and hold LRF harmless from any such biohazards whether known or unknown.**

### **13. Defaults**

If the LRF FL Grantee or Sponsoring Institution fails to follow or adhere to any policy or requirement expressed in this POLICY STATEMENT, ELIGIBILITY AND TERMS AND CONDITIONS GOVERNING GRANTEESHIPS or fails to carry out the research supported by the LRF Grant, LRF may terminate the LRF FL Grant and the LRF FL Grantee or Sponsoring Institution must return any remaining funds and without limiting LRF's rights or remedies.

### **14. Arbitration**

Any dispute between LRF and the Applicant, LRF FL Grantee or Sponsoring Institution that cannot be resolved informally shall be resolved exclusively through confidential arbitration in New York, New York in accordance with the rules of the American Arbitration Association. In no event will LRF be liable for any indirect, consequential or exemplary damages in such arbitration or otherwise and in no event shall LRF be liable for any damages in excess of the amount, if any, that LRF granted to the LRF FL Grantee less any amounts that the LRF FL Grantee actually received from LRF.

### **15. Sharing of Information, Biological Reagents, and Patents**

The LRF FL Grantee and Sponsoring Institution each agree to share all information, discoveries, or ideas arising out of research funded in whole or in part by LRF with LRF and the medical community at large.

Biological reagents (e.g. recombinant DNA clones, cultured cell lines, hybridoma cell lines, mutant or unique organisms) developed during the course of LRF-sponsored research must be made available to qualified investigators after the publication of reports using or describing the reagents. These materials represent a valuable resource for the scientific community at large, paid for by the generous contributions of LRF's donors. The availability of these reagents directly affects the ability of the members of the scientific community to replicate the experiments of others and the pace and cost of future research. Therefore, LRF requires that the LRF FL Grantee and Sponsoring Institution accept the responsibility of providing biological reagents developed during the course of LRF-sponsored research when reasonably requested to do so by other investigators.

The LRF FL Grantee and Sponsoring Institution shall inform LRF whenever a patent application arising out of research funded in whole or in part by LRF is submitted in any country, and will send LRF a photocopy of any such patent applications. The FL Grantee and Sponsoring Institution agree to abide by the LRF Patent and Intellectual Property Policy, which follow.

#### **15 (a) Patent and Intellectual Property Policy**

All inventions or intellectual properties (hereinafter called the "Properties") that result from support from the LRF, in whole or in part, of research, training grants, or other awards, must be reported at the earliest possible time to LRF. The Sponsoring Institution agrees to notify LRF immediately of the decision to apply for letters of patent or other legal protection for intellectual property in any country. Each LRF FL Grantee further agrees to seriously consider, in good faith, any comments, suggestions or objections that LRF may have concerning such applications. LRF

agrees to keep confidential and not to release any non-public information relating to such inventions, intellectual property or applications for intellectual property protection to any third party, except as specifically set forth below. All patenting expenses or intellectual property application expenses shall be borne solely by the Sponsoring Institution.

Title to all Properties will reside in the Sponsoring Institution to the extent that such title is claimed by the Sponsoring Institution under its published patent policies and procedures. If a Sponsoring Institution has no published patent policy or procedure administering inventions or intellectual property, or if the institutional patent policy or procedure does not claim rights for the institution or individual inventor, then LRF shall have the right to determine the disposition of the rights in the Properties in accordance with the provisions set forth below.

Distribution of income or other consideration derived from any Properties, shall be made in accordance with the policies of the Sponsoring Institution, however, such distribution shall be guided by the principle that LRF's proportion of the income shall be reasonably related to LRF's proportion of support for the research leading to any Properties.

Notwithstanding any of the foregoing, if any Properties are made with the joint support of LRF and any agency or department of the United States Government, LRF may defer, in its sole discretion, to the patent policy of such agency or department upon receipt of a written statement by the appropriate government agency or department notifying LRF of its position with respect to the invention in question.

With respect to any Properties that result from the joint support of LRF and another organization that is not an agency or department of the United States Government, that organization, the LRF FL Grantee, the Sponsoring Institution, and LRF will confer, in good faith, to arrive at a mutually satisfactory disposition of rights to the Properties.

No patent, patent application, or other type of protection for the Properties, shall be abandoned or permitted to be abandoned, by operation of law without first notifying LRF. At such time, the Sponsoring Institution shall give LRF reasonable opportunity to take title to the Properties and any related application for intellectual protection.

The Sponsoring Institution agrees that when it licenses the Properties, it will obligate the licensees in accordance with the following: The licensee shall agree to exert its best efforts to commercialize or cause to be commercialized, the Properties as rapidly as practical, consistent with sound and reasonable business practices and judgment. In the event the licensee has failed to commercialize the Properties within a 3-year period, the Sponsoring Institution, upon conferring with LRF, shall have the right to convert an exclusive license to a non-exclusive license or terminate an existing non-exclusive license with such licensee. If the licensee has an ongoing and active research, development, manufacturing, marketing, or licensing program appropriately directed toward the production and sale of the Properties, then this would be deemed to be sufficient evidence that the licensee has commercialized the Properties.

LRF reserves the right to public acknowledgement for the Properties resulting from research that LRF has supported. However, LRF's name and logo may not be used in association with any Properties or otherwise without the prior written approval of LRF in each case.

LRF may have use of the Properties without payment of royalties or license fees solely for the use by LRF for its own intramural or public education purposes.

### **16. Confidentiality**

All LRF applications, application evaluations, and priority scores are considered confidential and are made available only to the SAB, the Board, administrative staff and other LRF representatives involved in the application process. Written critiques of applications and priority scores are not made available to Applicants. Although LRF endeavors to protect the confidentiality of proposal and evaluation materials, confidentiality cannot be guaranteed. Submitted proposals become the property of LRF and will not be returned.

### **Timeline:**

March 2009	Notification of Award
July 2009	Commencement of Funding
August 2010	First Year Progress report due
August 2011	Second Year Progress report due
June 2012	Termination of Project
August 2012	Final Report and Accounting Report due; return of unused funds.