



THE TRANSLATIONAL RESEARCH
PROGRAM
GUIDELINES & INSTRUCTIONS

FOR

NEW
LETTER OF INTENT
&
FULL APPLICATION

December 1, 2015

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GUIDELINES

ABOUT THE LEUKEMIA & LYMPHOMA SOCIETY

The Leukemia & Lymphoma Society (LLS) is the world's largest voluntary health agency dedicated to funding blood cancer research, education and patient services. LLS's mission: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

The Translational Research Program (TRP) was developed to encourage and provide early-stage support for clinically translatable research in leukemia, lymphoma and myeloma, which is intended to develop innovative approaches to treatment, diagnosis or prevention. A description of LLS's grant portfolio is found by following this link: <http://forms.lls.org/FormRenderer/grants/search>

DESCRIPTION OF AWARDS

The formation of the Translational Research Program (TRP) was to foster collaboration between basic and clinical scientists with the intent of enhancing the transfer of basic research findings to clinical usefulness.

Applications are sought proposing novel approaches to the prevention, diagnosis or treatment of hematological malignancies and related pre-malignant conditions. Proposals should be based on molecular, cellular or integrated systems findings and be conceptually innovative. The application should have a clear plan for the clinical translation of the studies proposed and the results expected. This feature will be an important consideration of the review process.

This program is intended to provide support over an initial three-year period. Two additional years may be available through the competitive, peer-reviewed TRP Renewal process to solidify progress made in the initial award and further support a clinical trial. To be considered for a TRP renewal award, a clinical protocol for a Phase I or Phase II clinical trial based on the initial Translational Research Program grant must be submitted to the institution's IRB for approval and the work must be a direct result of the funded TRP award (see Renewal Guidelines and Instructions for detailed information).

Table 1: Maximum TRP Award Duration & Value

***Please note: The TRP award amount you are given will reflect the amount you request in the budget section of your application. Any requests to increase funding must be in writing to LLS and are subject to the availability of funds.**

Duration	Maximum Annual Direct Costs	Maximum Annual Indirect Costs	Maximum Total Costs	Maximum 3 Years
3 yrs	\$180,018	\$19,982	\$200,000	\$600,000

WHO CAN APPLY

Citizenship and Degree

Applicants must hold an M.D., Ph.D., or equivalent degree, and work in domestic or foreign non-profit organizations, such as universities, colleges, hospitals or laboratories. Applications may involve multiple such institutions and the Applicant should have an independent research or academic position. Applicants need not be U.S. citizens, and there are no restrictions on Applicant age, race, gender or creed.

Applications from non-academic facilities, post doctoral positions and the National Institutes of Health are not eligible.

LEADERSHIP AND STAFFING

A Principal Investigator may only submit ONE application per application cycle and cannot serve as a Principal Investigator OR Co-Principal Investigator on more than ONE application per cycle. A Co-Investigator (also known as Collaborator) CAN serve as Co-Investigator on more than one application with no limit. Members of the peer review committee cannot apply for a TRP award. They may apply for a renewal award if they are not serving on the renewal committee since these are awarded independently of the regular TRP awards.

The Application will require one Principal Investigator who is responsible for the preparation and submission of the proposal including budget, the conduct of the research programs and adherence with all stipulations made by LLS in this document, the Policies & Procedures document, and in the grant contract if funded. Co-investigators are allowed on multiple applications; however one individual is to be designated as the Principal Investigator and this individual is limited to one application only.

An Applicant may only submit one new application and/or one Renewal application per award cycle.

APPLICATION PROCESS AND DEADLINES

Registration

Both the Applicant and Sponsoring Institution must be registered in Fluxx. If you have applied to LLS in the past, you do not need to create a new registration. Simply click the “reset or create password” link and enter your email address. The system will send your username and a link to update your password. Once registered, the Applicant can begin the LOI. Email researchprograms@lls.org for assistance creating a new account in Fluxx if you do not already have one. Only LLS staff members have administrative permission to create new accounts.

Data Entry

Both the LOI and the full application may be accessed and changed multiple times as needed prior to the submission deadlines. However, **neither the LOI nor full application can be changed once the deadline has passed or the application has been finally submitted.** Moreover, some fields may not be modified in the full application following submission of the LOI.

Contacting LLS

Questions that are not clarified in this document or in the tutorial on the Fluxx site should be addressed to researchprograms@lls.org.

Relevance

The proposed research should be clinically directed or clinically translatable in hematologic malignancies that is intended to develop innovative approaches to treatment, diagnosis, or prevention. Projects currently funded by LLS can be viewed under the Grant Finder section of the LLS website at <http://forms.lls.org/FormRenderer/grants/search>.

Forms and Format

An application template is provided on the Fluxx website during the Full Application phase. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when Applicants populate fields on the Fluxx website. Fields in bold are required. Other information will be captured using the provided template. All Applicants must use single-spaced text and 12 pt. Times New Roman. Margins are preset in the template and must remain as is. The Applicant's name should be typed in the upper right corner of each page of the template. Failure to use the provided template or to adhere to font size, spacing, margins, and/or page limitations may result in the disqualification of the application.

REVIEW PROCESS OF LOI

Letters of Intent are reviewed and approved by LLS at the time of submission. Once the LOI has been approved, the Full Application will immediately be available to the Applicant on Fluxx for submission. The deadline to submit a Full Application is March 1st.

Full Applications will only be accepted via Fluxx. The submission deadlines will be strictly enforced. Please note that all times are Eastern Time (ET). If any date falls on a weekend or a U.S. holiday, the deadline becomes the following business day.

Table 2: TRP Grant Application Deadlines

Application Phase	Date	Time
Letter of Intent – open	December 3, 2015	
Letter of Intent – close	January 25, 2016	3:00pm ET
Full Application – close	March 1, 2016	3:00pm ET

REVIEW CRITERIA

An application will be judged on these criteria:

- The probability of an advance in prevention, diagnosis or treatment in the near-term.
- The conceptual basis upon which the proposal rests.
- The novelty of the concept and strategy.
- Thoughtful and clear presentation.
- The overall plan for bringing the research findings to clinical application.
- Experience, background, and qualifications of investigators.
- Adequacy of resources and environment (facilities, access to patient samples if needed, data management, and data analysis, etc.).
- Adequacy of provisions for protection of human subjects.

REVIEW PROCESS OF FULL APPLICATIONS

Full Applications will be reviewed after the March 1st submission deadline by the TRP Subcommittee of the Medical & Scientific Affairs Committee. If an application does not meet the program goals, scope, or guidelines, it will be administratively disqualified. Once ranked, a priority score and funding recommendations of the TRP Subcommittee will be presented to the Medical & Scientific Affairs Committee and Mission Oversight Committee for final determination of awardees (in June). The Mission Oversight Committee will determine the number of awards funded, based on scientific merit and the budget approved by LLS's National Board of Directors.

Any Applicant selected for funding will be notified within 45 days of the funding decision. **Funding decisions are relayed by email and postal mail only and are not available by telephone.** All priority scores are confidential in that they are available to LLS's Medical & Scientific Affairs Committee, LLS's Mission Oversight Committee, its Research Subcommittee and administrative personnel only.

Applications are assigned an initial score by the primary and secondary reviewer. Only applications that fall above a scoring level determined by the committee chair will be discussed in detail for final ranking by the entire committee.

GENERAL INFORMATION

LLS is using Fluxx as our online grants management system, which is accessed here: <https://lls.fluxx.io>. Only online submissions through the Fluxx website will be accepted.

Institutional Designation

During the registration process, Applicants should create their profile from the standpoint of where they will perform their research described in the application. The Applicant must indicate the name of the Sponsoring Institution as well as the name of the signing officials for that institution. Fluxx currently has a list of organizations registered. To register a new institution, contact researchprograms@lls.org.

Data Entry

Both the LOI and the full application may be accessed and changed multiple times as needed prior to the submission deadline. However, neither the LOI nor the full application can be changed once the deadline has passed or the application has been finally submitted. Moreover, some fields may not be modified in the full application following submission of the LOI.

Contacting LLS

Questions that are not clarified in this document should be addressed to:

Director, Research Administration
The Leukemia & Lymphoma Society
1311 Mamaroneck Avenue, Suite 310
White Plains, New York 10605
researchprograms@lls.org

Forms and Format

Applicants will provide information on the Fluxx website at the LOI phase; there is no other template necessary at this phase. For the full application phase, a template will be provided on the Fluxx website. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when Applicants populate fields on the Fluxx website. Fields in bold are required. All Applicants must use single-spaced text and Times New Roman 12 pt. Margins are preset in the template and must remain as is. The Applicant's name should be typed in the upper right corner of each page of the template. Failure to use the provided template or to adhere to font size, spacing, margins, and/or page limitations may result in the disqualification of the application. In addition, character limitations must be adhered to.

LETTER OF INTENT

Each Applicant must submit the LOI by **January 25th at 3:00pm ET** via the Fluxx website (<https://lls.fluxx.io>), or the following business day if this date falls on a weekend or a U.S. holiday. The Applicant should carefully craft the information requested in the LOI as this information is automatically populated into the full application and is subject to the Changes clause listed below.

The LOI will be evaluated by staff on a rolling basis. If the LOI is approved, the Applicant will be notified by automated email from Fluxx that they may proceed to the next phase of the application process.

Completing the LOI

ORGANIZATION INFORMATION

Sponsor Institution and Department

Indicate the name of the sponsoring institution and department. If this institution is not listed, please contact researchprograms@lls.org.

Principal Investigator

The Principal Investigator is the Applicant.

Institutional Signing Official (ISO)

The ISO is the institutional representative responsible for the signing and agreeing to the accuracy of the application and the terms of the award, should the application be selected for funding.

Financial Officer

The Financial Officer is the institutional representative responsible for the financial administration of externally-funded research.

Additional Access (Admin/Assistant)

Access may be given to personnel to assist in the application process. This is the institutional representative responsible for the day-to-day administration of externally-funded research (or the Research Administrator).

Technology/Transfer Official

The Technology Transfer Official is the institutional representative responsible for overseeing Intellectual Property.

Zip Code of Sponsoring Institution

Enter the Zip Code of the Sponsoring institution.

PROJECT OR PROGRAM INFORMATION

Choose the Basic Translational Research Program option from the drop-down menu if you are submitting a new application. If you are applying to the Renewal program, check the corresponding box in the drop-down menu, provide the previous TRP grant number, then refer to the Renewal Guidelines to complete your application.

REQUEST PROPOSAL INFORMATION

This year there are five RFP topics in research areas that highlight unmet need. If your proposed research falls within a topic listed, please choose “Yes” from the selections. Otherwise, choose “No”. Choosing “No” for all topics does not disqualify your application from review. An outstanding proposal could be funded even if it does not adhere to the RFP topics. The research topics are as follows:

1. **Personalized medicine approach for cancer treatment.** Advances in cancer care have significantly improved lives of patients with hematologic diseases such as CLL, CML, Hodgkin Lymphomas, and ALL. LLS believes that, with time, complete cures can be achieved for certain blood cancers. Therefore, LLS will continue to support research that may revolutionize cancer care for hematologic diseases through the use of state of the art technologies for molecular profiling, early disease detection, prognostic/predictive biomarkers and novel target identification, as well as patient selection.
2. **Development of novel therapies and/or novel therapeutic strategies including those that target mutational and epigenetic events within the microenvironment. Such therapies can be applicable to any hematologic malignancies but emphasis is warranted in the following areas:**
 - a. Aggressive subtypes of Non-Hodgkin Lymphoma including but not limited to DLBCL, tFL, PTCL, and ALCL
 - b. Multiple myeloma including MGUS/SMM.
 - c. Indolent lymphoma including but not limited to CLL, MCL, FL, WM (therapies with the potential to provide significant extension of lives of patients or total disease control in defined subtypes).
 - d. Myeloid disorders including MPN/MDS/AML.
 - e. Pediatric and adult ALL (LLS is particularly interested in therapies that can avoid harmful chemotherapy and is effective even in relapsed ALL).
3. **Improvements in the safety and efficacy of stem cell transplantation.**
4. **Long-term outcome assessment following therapies.**
5. **Establishment of patient registries, particularly those associated with clinical trials, to advance patient care.**

GRANT INFORMATION

Project Title

Provide a title adhering to the 100 character limitation (which includes spaces).

Project Summary

Provide a title adhering to the 500 character limitation (which includes spaces). Charts and graphs should not be included in the project summary section.

Scientific Abstract

Briefly describe the proposed research in 3,000 characters or less using technical language. Once the LOI has been submitted, the scientific abstract may not change. Greek characters or symbols must not be used.

Lay Abstract

Clearly state in lay language the proposed research in 3,000 characters or less. Once the LOI has been submitted, the lay abstract may not change. Greek characters or symbols must not be used.

Amount Requested

The total amount, including both direct and indirect costs, cannot exceed \$200,000/year. Enter the total amount of funding requested over the life of the grant (Maximum \$600,000).

Proposed Start Date

The start date for all TRP grants is October 1st in the year the award is made (i.e. if an award is made to your application in July 2016, the grant start date will be October 1st, 2016).

Proposed End Date

The end date for all TRP grants is September 30th three years after the year the award is made (i.e. if an award is made to your application in July 2016, the grant end date will be September 30th, 2019).

Previous Submission

Indicate whether you have previously submitted this proposal (or one similar) to LLS, and indicate the date of any prior submission.

KEY PERSONNEL OR COLLABORATORS INFORMATION

New collaborator or key personnel contacts may be added to the collaborator section by clicking the green plus sign. These include Co-Principal Investigators and Co-Investigators.

If you plan to submit an application or serve as Co-Principal Investigator on an application, you will not be eligible to serve on the program’s review panel this cycle.

BIOSKETCH

A biographical sketch is required for the Applicant. It is acceptable for the Applicant to use their NIH biosketch. Include a biosketch as needed for key personnel on the project. When listing all government and non-government support in the Other Research Support for the Applicant and other key personnel, **the applicant must indicate any overlap of aims or research efforts of proposed work receiving funding in addition to the LLS requested funding.** No more than one biosketch per individual should appear in the application.

SAVE AND REVIEW

Validation will automatically occur after clicking the “Save” button. Validation is a safety measure for the Applicant to ensure that all required fields are complete. If required fields are empty or incomplete, the system notifies the Applicant of fields that require information.

After clicking “Save” you will be directed to review your LOI. Please ensure all information is accurate, and then click the “Submit” button to submit your LOI.

SUBMIT

The Applicant can formally submit the LOI using this function. Signatures of the Applicant and Sponsoring Institution are not required for submission of the LOI.

CHANGES

Information collected in the LOI will automatically populate fields in the full application. Once submitted, changes may only be made after receiving prior approval from LLS. The Applicant must email LLS (researchprograms@lls.org) requesting any change and identifying the elements to be changed. Any changes made without the prior approval of LLS may result in the disqualification of the application.

SUBMISSION OF THE LOI

Each Applicant must submit the LOI by **January 25th at 3:00 pm Eastern Time** via the Fluxx website, or the following business day if this date falls on a weekend or a U.S. holiday. After clicking the “Submit” button, the Applicant will receive an email from Fluxx stating that the LOI was successfully submitted. **If you did not receive the confirmatory email from Fluxx within 2 business days of LOI submission, please e-mail researchprograms@lls.org.**

REVIEW OF THE LOI

LLS staff will process LOIs as they are submitted. After the LOI is reviewed, the Applicant will be notified via automated email whether or not they have been invited to submit a Full Application. If invited for Full Application submission, the Applicant will have access to this section in the Fluxx grant management system. If you have not received an email regarding your LOI approval within 2 business days, contact researchprograms@lls.org.

FULL APPLICATION

Each Applicant must submit a full application by **March 1st at 3:00 pm Eastern Time** via the Fluxx website (<https://lls.fluxx.io>), or the following business day if this date falls on a weekend or a U.S. holiday. Some sections of the full application will be automatically captured electronically on the Fluxx website from the LOI. Other pieces of information will be captured in the application template that must be downloaded, completed, and then uploaded by the Applicant. The Applicant may not modify any information provided in the submitted LOI as this is subject to the Changes clause listed above, and may result in disqualification of the application.

Completing the Full Application

PROJECT OR SUPPORTING DOCUMENTATION

- Log on to the Fluxx site (<https://lls.fluxx.io>), click “New Request” on the left, click on your application, then click “Edit”.
- Download and complete the Project Description/Budget template. The Project Description is limited to 7 pages.

The completed Project Description/Budget template and all appendices must be uploaded as one single PDF file.

Project Description/Budget Template

The Project Description/Budget template includes 4 fields, as follows: a) Project Description b) Other Research Support c) Budget d) Budget Justification.

Each Project Description is limited to 7 pages and should be presented in the following sequence:

- Title and Specific Aims (approximately 0.25 pages)
- Scientific and Clinical significance of the work (approximately 1.0 page)
- Previous Studies/Preliminary Data (approximately 2.5 pages)
- Research Methods (approximately 0.75 pages)
- Interaction with other Investigators (approximately 0.5 page)
- Resources and Environment (Major lab items or facilities) (approximately 1.0 page)
- References cited (approximately 1.0 page)

Budget

The Detailed Budget and Budget Justification should provide itemized detail for each major category for the all years of the program. This budget can be summarized in Year One of the budget and extrapolated for the remaining three years. All Totals and Subtotals should be completed on the form.

The maximum annual total cost (direct and indirect) cannot exceed \$200,000. The aggregate costs over three (3) years cannot exceed \$600,000.

Permissible Direct Costs include the following with the specified limitations:

- Personnel Expenses including salary, wage, or stipend with fringe benefits. In total, no more than forty percent (40%) of the direct costs may be requested for the salary and fringe benefit expenses of professional staff with a post-graduate degree (i.e. M.D., Ph.D., D.V.M.) regardless of function or role. This restriction does not apply to technical staff (lab assistants, nurses, etc.).
- Supplies & Materials requests should be itemized by category.
- Equipment Purchase requests must identify each item of equipment with an acquisition cost of more than \$500.
- Travel Expense requests cannot exceed \$1000 per year of the award.
- Other Direct Cost requests can include patient care costs.

Permissible Indirect Costs (often referred to as Institutional Overhead, IDC, M&A, G&A or pooled costs) are those costs incurred for common or joint objectives that cannot be readily identified with a particular project (general maintenance, utilities, library, etc.) as defined in Office of Management and Budget Circular A-21. Indirect costs are limited to (11.1%) of total direct costs. For Sponsoring Institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the Grantee's/Principal Investigator's stipend or fringe benefits cost.

Impermissible Costs include membership dues, tuition, books, journals, and publication costs.

SIGNATURE PAGE

All applications must be signed by the Principal Investigator (and Co-Principal Investigator if applicable), Institutional Signing Official, Research Administrator, Financial Officer, and Technology/ Transfer Official. The signature page is provided in the downloadable application template. The Grants and Contracts Office of the Sponsoring Institution can help ensure appropriate signatures are obtained.

- **Principal Investigator**
The Principal Investigator is the Applicant.
- **Financial Officer**
The Financial Officer is the institutional representative responsible for the financial administration of externally-funded research.
- **Research Administrator**
The Research Administrator is the institutional representative responsible for the day-to-day administration of externally-funded research.
- **Institutional Signing Official (ISO)**
The ISO is the institutional representative responsible for the signing and agreeing to the accuracy of the application and the terms of the award, should the application be selected for funding.
- **Technology/Transfer Official**
The Technology Transfer Official is the institutional representative responsible for overseeing Intellectual Property.
- **Co-Principal Investigator**
The Co-Principal Investigator is the Co-Applicant.

UPLOAD THE PROJECT TEMPLATE - REQUEST, PROJECT, AND SUPPORTING DOCUMENTATION

Upload the completed template as one single PDF to the Request, Project, and Supporting Documentation section by clicking the green plus sign. Choose “Project Description” from the drop down menu before uploading.

ORGANIZATION ASSURANCES

The Applicant must complete the organization assurances section. The following provides an overview.

Human Subjects

The Applicant must indicate if human materials or subjects will be involved in the proposed research. The status (approved, pending or exempt) of Institutional Review Board (IRB, or equivalent oversight entity) approval must be provided. The Human Subject Assurance Number (OHRP) must be included. If the research project has received IRB approval, the date must be provided and documentation must be uploaded as the Human Investigation Statement. The application may be submitted with IRB approval pending. However, an award will not be made without documented IRB approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the May review date if the IRB status has changed. If a project is exempt from IRB review, the certificate of exemption must be uploaded as the Human Investigation Statement.

Laboratory Animals

The Applicant must indicate if laboratory animals will be involved in the proposed research. The status and date of Institutional Animal Care and Use Committee (IACUC, or equivalent oversight entity) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of Sponsoring Institutional approval must be uploaded as the Laboratory Animal Statement. The application may be submitted with IACUC approval pending. However, an award will not be made without documented IACUC approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before the May review if the IACUC status has changed.

Recombinant DNA

The Applicant must indicate if the proposed research involves the use of recombinant DNA. Documentation of Sponsoring Institutional approval must be uploaded with the application.

Biohazard Statement

The Applicant must indicate if the proposed research involves the use of biohazards. If the Applicant indicates affirmatively, then an institutional statement of assurances regarding potential biohazards and safeguards must be uploaded as the Biohazard Statement.

Clinical Protocol Appendix (if applicable)

Provide a one page summary and a link to the clinicaltrials.gov website for any clinical protocol essential to the proposed research. Include IRB approval date, IRB compliance number, and effective dates of approval. Projects for which IRB approval is pending must include a statement to that effect. The Applicant should notify LLS of IRB approval prior to the May grant review.

BUDGETING INFORMATION

Enter the budgeting information as required on the web form fields.

APPLICANT ASSURANCE

Check the box to accept the terms as stated on the web form field.

SAVE AND REVIEW

Validation will automatically occur after clicking the “Save” button. Validation is a safety measure for the Applicant to ensure that all required fields are complete. If required fields are empty or incomplete, the system notifies the Applicant of fields that require information.

SUBMIT

After clicking “Save” you will be directed to review your application. Please ensure all information is accurate, and then click the “Submit” button to submit your application.

Once submitted, only LLS staff can delete the file. If you need a file deleted from the upload section, contact researchprograms@lls.org for assistance.

If you plan to withdraw your application at anytime during the application cycle, please inform LLS staff of your decision by writing to researchprograms@lls.org.

REVIEW OF THE FULL APPLICATION

An independent committee will review properly submitted applications. Please check Fluxx for the status of your application. Please do not call or email LLS to determine whether the application has been received, when it will be reviewed, or the results of the review. This information will be communicated via email.

APPLICATION SCORING OVERVIEW

The LLS will continue to pursue proposals in several specific research areas that it considers “high unmet need”. Applications that focus on one of the RFP topics, detailed on page 8 of this document, will be given funding priority within our Translational Research Program (TRP):

Each application will receive two scores: The **Priority Score**, with a range from 1-9, will be based on a clear plan for the clinically translatable exploitation of the studies proposed and the results expected. Proposals should be based on molecular, cellular or integrated systems findings and be conceptually innovative. This feature of the proposal will be an important consideration of the review process.

While work directed at a further elucidation and understanding of the fundamental cellular and molecular biology of neoplastic lymphohematopoietic cells is a research priority of LLS, the Translational Research Program is specifically intended for the support of work which is clearly clinically translatable and will be scored in a manner that is reflective of that premise.

Reviewers will also assign a **Mission Score** based on the following categories:

Mission Score of 1 – There is a very high degree of integration between basic and translational research with **strong potential** to lead to a clinical trial in the field of blood cancer during the duration of the award.

Mission Score of 2 – There is a very high degree of integration between basic and translational research with a **moderate potential** to lead to a clinical trial in the field of blood cancer during the duration of the award.

Mission Score of 3 – There is a moderate degree of integration between basic and translational research with a **low potential** to lead to a clinical trial in the field of blood cancer during the duration of the award.

TRP applications will be rank ordered based on their Overall Priority Score (10-90; which reflects the average of all the reviewers’ priority scores multiplied by ten). **When scores are close in value**, applications with a Mission Score in category 1 may be funded although their Priority Score is less meritorious than those of other applications in Mission Score categories 2 and 3. Only applications with scores in the excellent to exceptional range (Overall Priority Score between 10 and 30) will be funded, regardless of mission category rankings.

The award is capped at \$200,000/year for 3 years (\$600,000 total).