Academic Clinical Trials Program Guidelines & Instructions

Effective dates:
August 29, 2022 – June 30, 2023

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Key Points

- It is highly recommended to access the LLS Research Portal at https://lls.fluxx.io to begin the application process well in advance of any deadlines.
- It is recommended that final submissions at each stage (letter of intent/full application) be completed well before the deadline.
- All components of the application must be presented in the order indicated in these guidelines.
- All information must be typed in English using commonly accepted grammar and punctuation. All applicants must use single-spaced text and Arial size 11 font (figures and references must also be Arial size 11 font). Figures which are not legible or too small will impact the ability of reviewers to evaluate your application and may reflect in the final scoring. Margins are preset in the templates and must remain as set. LLS uses *Blood* citation format for references.
- Completion of several steps in the process initiates emails sent from the LLS Research Portal. LLS staff may also send emails during the application process. Spam filters should be monitored for these emails.
- Contact researchprograms@lls.org if expected emails are not received by the times indicated in these guidelines or if you have any questions not clarified in this document.
- Do **not** attach documents to the application that are not specifically called for. ***The application could be administratively triaged if this rule is violated.***
- You may apply to more than one grant program during an application cycle if the aims do not substantially overlap with the aims of any other application across all programs.
  In addition, you may have the same investigator(s) as PI(s), Co-I(s), Project or Core Leaders, or collaborator(s) on a different project provided the aims differ.
  All such duplicate grant proposal submissions with substantially overlapping aims are subject to administrative disqualification, and such proposals will not be reviewed further or considered for funding. Contact researchprograms@lls.org with any questions about this policy or to discuss with LLS scientific staff any questions concerning potential overlap between applications.

About The Leukemia & Lymphoma Society, Inc.

The Leukemia & Lymphoma Society, Inc. (LLS) is a national voluntary health agency dedicated to the conquest of hematologic malignancies and relevant premalignant conditions. LLS supports research, patient aid, community service programs, advocacy, and public and professional education.

Description of Awards

The purpose of the Academic Clinical Trials Program (ACT) is to enhance the development and implementation of academic investigator initiated clinical trials (IIT) in the hematological malignancy space.

Applications are sought proposing novel approaches to the treatment of hematological malignancies and related pre-malignant conditions. The primary focus will be IIT Phase 1 or 2 trials investigating novel agents in any hematological disease either as single agents or in combination therapies. Any therapy type whether biological or chemical is eligible. The focus of the research must be a clinical trial; however, additional aims can address topics such as correlative studies, biomarker investigations, etc. Repurposing of existing agents into novel diseases will also be considered. **LLS is seeking truly novel advances and not simply incremental advances of existing agents.** Existing trials or expansion of existing trials are eligible to apply.

Investigation of corporate owned assets is allowed. If a corporate asset is used, a clear path to market must be obtained and demonstrated.

Maximum ACT Award Duration & Value

Maximum Duration	***Maximum Annual Direct Costs***	***Maximum Annual Indirect Costs***	***Maximum Award Total***
3 years*	TBD at Launch	15% of Annual Costs	Up to $1M

Direct costs for salary and fringe benefit expenses must only be for the actual costs for the proposed work.

***The proposal must reflect the actual time and funding required.**

The final budget for these awards will be determined based on the amount requested in the application and is subject to change by LLS prior to signing the funding agreement. A payment schedule as well as quarterly progress meetings will also be determined at this time. It is anticipated that LLS will award 20% of the total agreed upon budget at grant launch. Further payments will be designed around the quarterly progress meetings and tied to any agreed upon milestones based on clinical progress/patient accrual, etc. A Gantt chart and/or specific milestones for the trial are required at the full application phase.

Furthermore, LLS recognizes that due to the nature of clinical research the final budget will serve as a guideline that can be altered based on resource needs as the trial progresses. LLS reserves the right to terminate at our sole discretion if it is deemed that insufficient progress is being made in a timely manner towards the goals of the trial.

Who Can Apply

Citizenship

LLS welcomes applications worldwide from appropriate not-for-profit academic institutions and investigators of any nationality.

Degree

Applicants must hold a PhD, MD, DVM, or equivalent degree. Non-independent investigators such as post-docs, instructors, etc. are not qualified.

Funded Institution's Acceptance of the Terms and Conditions

Applicants who are offered an ACT award will be sent a funding agreement. The funded institution's representatives must agree to these terms and conditions and return the signed agreement by the deadline. Currently, the NIH does not accept LLS's contract terms.

Leadership and Staffing

A Principal Investigator or Co-Principal Investigator may only submit ONE application per application cycle. Additional Senior staff (also known as Collaborators) CAN serve as Collaborators on more than one application with no limit. A Principal Investigator or Co-Principal Investigator can serve as a Collaborator on other applications.

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 Funding Agreement, if funded. Co-Principal 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 per award cycle. The ACT program is intended for independent, established researchers. Therefore, applicants holding positions such as post-doctoral fellows, instructors, etc. are discouraged from applying.

Relevance

The proposed research must be clinically directed in hematologic malignancies that is intended to develop innovative approaches to treatment of disease. Additional aims that explore correlative studies, mechanistic investigation, biomarker validation, etc. are allowed if the main focus of the award is on the clinical trial.

Review Process & Applicant Notification

The deadline to submit all Letters of Intent (LOI) is October 28, 2022, at 3 PM ET. Letters of Intent are reviewed after the LOI deadline. Once the LOI has been reviewed, the applicant will be notified via an automated email as to whether or not they have been invited to submit a full application. If invited for full application submission, the applicant will immediately have access to this phase in the LLS Research Portal. If you have not received an email regarding your LOI approval by November 23, 2022, contact researchprograms@lls.org.

The deadline to submit all full applications is January 17, 2023, at 3 PM ET. Full applications will only be accepted via the LLS Research Portal (https://lls.fluxx.io).

Key Dates

	Date
Call For Proposals	August 29, 2022
Letter of Intent due	October 28, 2022, 3:00 PM ET
Full Application due	January 17, 2023, 3:00 PM ET
Panel Review Meeting	Mid-March 2023
Award Notification	May 2023
Award Start Date	July 1, 2023

Future Bi-Annual Funding Cycle. Based on future need, LLS may open ACT on a bi-annual basis; opening would be in May 2023 with funding starting in October 2023.

All submission deadlines will be enforced. Please note that all times are Eastern Time (ET). If any date falls on a weekend or US holiday, the deadline becomes the next business day. There are no exceptions permitted.

It is highly recommended that submissions are done *prior* to the deadline. Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the deadline. Therefore, it is imperative that any questions be posed to LLS as far ahead as possible. The LLS Research Portal automatically shuts down submissions after the deadline has passed. **Late submissions due to technical difficulties will not be accepted**. Every year, a few applicants get caught with difficulty near the deadline; some are unable to submit because of these issues. The best way to avoid this problem is to submit every phase well ahead of the deadline.

Review Criteria

An application will be judged on these criteria:

- The probability of an advance in the treatment of the disease being investigated.
- A well-designed trial with criteria clearly defined to achieve the goals stated.
- Diseases with **high unmet** need and proposals with truly **novel agents or mechanistic pathways** that open new therapeutic avenues **will be highly favored.**
- The conceptual basis upon which the proposal rests.
- The novelty of the concept and strategy.
- Thoughtful and clear presentation.
- The impact of the research beyond incremental improvements.
- Experience, background, and qualifications of investigators.
- Adequacy of resources and environment (facilities, patient population, data management, and data analysis).
- Adequacy of provisions for protection of human subjects.
- A clear path to market for corporate owned assets must be obtained and demonstrated.

Full Applications will be reviewed after the January 17, 2023, submission deadline by the ACT Subcommittee of the Medical & Scientific Affairs Committee. If an application does not meet the

program goals, scope, or guidelines, it will be administratively triaged. Applications are assigned an initial score by the primary and secondary reviewers. 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.

Recommendations of the ACT Subcommittee will be presented to the Medical & Scientific Affairs Committee and LLS's National Board of Directors for final determination of awardees. The Board of Directors will determine the number of awards funded, based on scientific merit and the budget approved.

Any applicant selected for funding will be notified by the date indicated in the Key Dates section**.** 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. Please check the LLS Research Portal for the status of your application. All applications are confidential in that they are available to LLS's Medical & Scientific Affairs Committee, its Research Subcommittee, LLS's National Board of Directors, and administrative personnel only. **Feedback will only be provided for applications discussed by the full review committee.**

General Application Instructions

All submissions must use the LLS Research Portal, Fluxx, at https://lls.fluxx.io/. It is recommended that you familiarize yourself with this portal well in advance of any deadlines.

Registration

Both the applicant and institution must be registered in the LLS Research Portal. If you have applied to LLS in the past, you do not need to create a first-time registration. If you forgot your password, 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 updated, the applicant can begin the LOI. If you are a first-time user to the LLS Research Portal, please complete the intake form located at this link: Account Creation Request so an account can be created for you. Only LLS staff members have administrative permission to create new accounts.

Institutional Designation

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 institution as well as the name of the signing officials for that institution. 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 final application has been submitted. Moreover, some fields may not be modified in the full application following submission of the LOI.

Forms and Format

Applicants will provide information on the LLS Research Portal and a downloadable template at the LOI and full application phases. All information must be typed in English using commonly accepted grammar and punctuation. Some information will be captured when applicants populate fields on the LLS Research Portal. Fields in bold are required. All applicants must use single-spaced text and Arial size 11 font (figures and references must also be Arial size 11 font). Figures which are not legible or too small will impact the ability of the reviewers to evaluate your application and may reflect in the final scoring. Margins are preset in the template and must remain as set. 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 will result in the disqualification of the application.*** In addition, character limitations must be adhered to.

Contacting LLS

Questions that are not clarified in this document or the LLS Research Portal should be addressed to researchprograms@lls.org.

Beginning an Application

- Read these Guidelines & Instructions in full.
- Log into the LLS Research Portal, under "Information" in the left navigation bar, click "Academic Clinical Trial Program." Click "Apply to ACT" to being the application process (well ahead of the deadline).
- Follow the instructions for each web form field. Bold font indicates required information.
- Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded templates. Font must be Arial 11 pt. If character limits and font restrictions are not adhered to, or the preset margins are altered, the application may not be reviewed and will be triaged.
- Carefully check every page of your application prior to submission. You are ultimately responsible for this submission, even if someone else submits on your behalf.
- You may save your work and return to it at any time by clicking "Save." Clicking "Submit" will lock your application and prevent further modification at that stage. Contact researchprograms@lls.org if you submit in error (must be at least one hour prior to the deadline).
- At any time during the application process, including after submitting your full application, you can check the status of your application by logging in to the LLS Research Portal, selecting your application (under Requests in either "New or Pending" or "Submitted"), and referring to the status in the yellow box at the top of the page.
- If you have any technical difficulties with the LLS Research Portal, please contact us at researchprograms@lls.org.

Detailed Letter of Intent Phase Instructions

Each applicant must submit the LOI by **October 28, 2022, at 3:00pm ET** via the LLS Research Portal (https://lls.fluxx.io). 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. There are two main aspects to the Letter of Intent Phase: all Fluxx webform fields and the "Previous Studies/Preliminary Data/Trial Summary" (2 page maximum) downloadable template for completion. As noted below, an **IND/IRB approval must**

be in place prior to the start of funding but is not necessary for the application phases.

The LOI for ACT will be reviewed after the deadline. If the LOI is approved, the applicant will be notified by an automated email from the LLS Research Portal stating that he/she may proceed to the full application phase. Applicants may also check the status of their LOI on the LLS Research Portal.

Organization Information: If the institution or officials are not listed, please contact researchprograms@lls.org.

Institution: Indicate the name of the institution where the research will be performed.

Principal Investigator: The Principal Investigator is the applicant.

Institutional Signing Official (ISO): The ISO is the institutional representative responsible for signing and agreeing to the accuracy of the application and the terms and conditions 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 (TTO): The TTO is the institutional representative responsible for overseeing Intellectual Property.

Zip Code of the Institution: Enter the zip code of the institution if located within the United States. You will need to select the zip code from the drop-down menu to ensure it is captured in the zip code field. If not located within the US, this can be left blank.

Grant Information

Project Title: Provide a title adhering to the 100-character limitation (which includes spaces).

Project Summary: Provide a short summary (approximately 2-4 sentences) in lay language. Charts and graphs cannot be included in the project summary section of the LLS Research Portal.

Brief Biography (for the PI only): A brief biography written for a lay audience. Approximately 1,000 characters including spaces.

Scientific Abstract: Briefly describe the proposed research in 3,000 characters (including spaces) 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 Description: Using lay language, clearly state the proposed research in 3,000 characters (including spaces) or less. Once the LOI has been submitted, the lay description may not

change. Greek characters or symbols must not be used.

Amount Requested: Enter the total amount of funding requested over the life of the grant (Maximum $1,000,000). The amount requested on the LLS Research Portal should match the budget section of the full application template. See Description of Awards section for annual maximums. Please note that LLS does not follow NIH guidelines for budgets. Please adhere to the LLS rules as outlined in this document.

Proposed Start Date: The start date for ACT grants is July 1, 2023.

Proposed End Date: The end date for ACT grants will be determined at launch.

Previous Submission: Indicate whether you have previously submitted a similar proposal to LLS and indicate the date of any prior submission.

Key Personnel or Collaborators Information: New collaborator or key personnel (internal or external to your institution) contacts may be added to the collaborator section by typing the name(s) into the box. These include Co- Principal Investigators and Senior Staff (also referred to as Collaborators). *This section helps LLS identify conflicts with reviewer assignments.*

Previous Studies/Preliminary Data/Trial Summary: Upload the Previous Studies/Preliminary Data/Trial Summary (2 page maximum) to the "Project and Supporting Documentation" section of the web form. Text, figures, and references must be written single spaced in Arial size 11 font. Only one PDF is accepted in this section, so delete any other documents uploaded during the process. **Note**: When uploading this template to Fluxx, please ensure you choose the correct file name which should read "Previous Studies/Preliminary Data/Trial Summary" which you can choose from the document upload drop-down menu. If the file name is incorrect, you will not be able to submit the LOI.

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 to LLS.

Submission of the LOI

Each applicant must submit the LOI by **October 28, 2022, at 3:00 pm ET** via the LLS Research Portal. After clicking the "Submit" button, the applicant will receive an email from the LLS Research Portal stating that the LOI was successfully submitted. **If you did not receive the confirmatory email within two business days of LOI submission, please e-mail researchprograms@lls.org.**

Signatures of the applicant and institution officials 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 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.

Detailed Full Application Phase Instructions

Each applicant must submit a full application by **January 17, 2023, at 3:00 pm ET** via the LLS Research Portal. Some sections of the full application will be automatically captured on the LLS Research Portal 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 as a **single PDF**. The applicant may not modify any information from the submitted LOI as this is subject to the "Changes" section listed above and may result in disqualification of the application.

Failure to submit as a single PDF in the order below may result in disqualification of the application.

Three sections are required in the uploaded PDF:

Section 1: Graphical Abstracts (1 page maximum)

You will provide two graphical abstracts (which may also include text) to describe some aspects of your research, such as signaling pathways, overall approach, etc. These provide reviewers with quick overviews of your research. These are similar to what is seen at the beginning of a Cancer Cell paper, though they must not be professionally developed (you will be judged on your ability to convey information in a simple manner, but you will not be judged on artistic ability).

Section 2: Project Description (11 page maximum)

Download and complete the project description template, including all required signatures, and upload to the "Project or Supporting Documentation" section of the web form. Margins are preset and must not be changed. Text, figures, and references must be written single spaced in Arial size 11 font.
Only one PDF is accepted in this section (Project Description Template combined with biosketch(es)).

The template consists of the following required elements:

a. Project Description (11 page maximum, including figures)

The following information should be provided in this order. The approximate length listed for each section in the sequence is not a strict limit for each section. It is up to the applicant to utilize more or less space for individual parts based off the specifics of their application.

- Title and Specific Aim (approximately 0.25 pages)
- Scientific and Clinical Significance of the Work (approximately 1.0 page)
- Previous Studies/Preliminary Data (approximately 3.0 pages)
- Clinical Trial Summary (approximately 2.0 pages)
- Research Methods (approximately 1.25 pages)
- Interaction with Other Investigators (approximately 0.5 pages)
- Resources and Environment (major lab items or facilities) (approximately 1.0 page)
- References Cited (approximately 1.0 page)
- Gantt chart and/or trial specific milestones (approximately 1.0 page)

For the Previous Studies/Preliminary Data and Clinical Trial Summary sections, insertion of HTML links or clinicaltrials.gov website links is allowed. Please do not upload manuscripts, IRB documents, or complete trial protocols. 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 grant review.

The applicant must provide information **if a trial is receiving funding from a sponsor,** specifically, how much money is to be received and what the funds will be used for. Additionally, if a corporate asset is being provided, any letters of support from the corporation must be included in the proper section of the application.

Use Arial 11 pt. font for text, figures, and references.

b. Description of Model Systems and Reagents

Provide information on the models, drugs, and reagents described in your project description. This will be an easily assessable resource for reviewers to understand what is described in more detail in the text and figures.

c. Budget

The Budget and Budget Justification should provide itemized detail for each major category for all years of the project. The budget can be summarized in year one and extrapolated for the remaining two years. All totals and subtotals should be completed on the form.

The aggregate costs over the two to three (2 to 3) years cannot exceed $1,000,000. The milestones and payments schedule are outlined under the “Description of Awards” section.

Permissible Direct Costs include the following with the specified limitations:

- Personnel Expenses including salary, wage, or stipend with fringe benefits. **Direct costs for the salary and fringe benefit expenses must be only for the actual costs for the proposed work.**
- Supplies & Materials requests should be itemized by category.
- Equipment Purchase requests must identify each item of equipment with an acquisition cost of more than $4,000.
- Travel Expense requests cannot exceed $2,000 per year of the award.
- Patient Care Costs (Inpatient/Outpatient)
- Subcontract Costs
- Other Direct Cost requests

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 the Office of Management and Budget, Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. ***Indirect costs are limited to 15% of the total costs requested.*** For institutions that do not choose to use these funds for indirect costs, LLS allows the funds to be applied to the Principal Investigator’s stipend or fringe benefits cost.

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

d. Budget Justification
2 page maximum.

e. Signature Page
This form must be completed, including the indicated signatures.

Section 3: Appendix

The following sections must be attached in this order to the end of the template (from Section 2) to create a single PDF. ***No other information may be provided in this section*.**

a. Principal Investigator's NIH Biosketch (This document is not required for Senior Staff/Collaborators but is required for the Co-Principal Investigator).
Use the most recent NIH biosketch format found on the NIH website. Publications submitted and under review should be indicated on the biosketch. An eRA Commons Username is not required.

b. Principal Investigator's NIH Other Support Document (This document is not required for Senior Staff/Collaborators but is required for the Co-Principal Investigator).
Use the most recent NIH Other Support Document format found on the NIH website. Must contain all current and pending support from any source. **In addition, specific aims must be listed for current and pending grants that may overlap or appear to overlap with the LLS application.** This includes any grants or portions of grants submitted to any organization, including LLS.

If funding decisions about potentially overlapping, pending grants become available following submission of an LLS application, LLS must be notified within five (5) business days of the applicant's receipt of that information.

LLS recognizes that some investigations, particularly those involving clinical trials, may require multiple funding sources, so overlap of specific aims with another grant may be appropriate and acceptable. The need for and details about such overlap should be clearly explained in the application. However, LLS will consider an applicant's other current grant support in its funding decisions. This may result in LLS funding only part of the grant or none of the grant, depending on the level of overlap. In addition, LLS reserves the right to adjust the level of funding of an awarded grant should another overlapping or potentially overlapping grant that was pending at the time of application submission be awarded to the applicant.

Failure to abide by LLS's rules on disclosure of current or pending support may jeopardize the funding of the current application and may affect future LLS funding decisions.

c. Co-Principal Investigator's NIH Biosketch (if applicable)
Use the most recent NIH biosketch format found on the NIH website. Publications submitted and under review should be indicated on the biosketch. An eRA Commons Username is not required.

d. Co-Principal Investigator's NIH Other Support Document (if applicable)
Use the most recent NIH Other Support Document format found on the NIH website. This form must contain all current and pending support from any source. **In addition, specific aims must be listed for current and pending grants that may overlap or appear to overlap with the LLS application.** This includes any grants or portions of grants submitted to any organization, including LLS.

e. Collaboration/Support Letters
Required if reagents critical for the research are to be obtained from non-commercial and/or commercial sources and are not currently available in your lab.

f. Assurances (Required)
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 the 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 included in the single PDF of the application. The application may be submitted with IRB approval pending but 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 grant review if the IRB status has changed. If a project is exempt from IRB review, the certificate of exemption must be included in the single PDF of the application.

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 institutional approval must be included in the single PDF of the application. The application may be submitted with IACUC approval pending but 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 grant 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 institutional approval must be included in the single PDF of 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 included in the single PDF of the application.

No attachments besides those listed above can be included in the Appendix.

Applications that include additional documents besides those requested may be administratively triaged.

Uploading the project document and final submission
All documents must be combined into a single PDF in the order listed above. Failure to submit as a single PDF in the order above may result in disqualification of the application. Upload the

full application components, as a single PDF, in the "Project and Supporting Documentation" section on the web form. The file upload should be labeled, "ACT Project Description/Application" which you can choose from the document upload drop-down menu.

Fluxx Webform Updates

- **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.

Submission & Confirmation

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 to LLS.

Once an application is submitted, only LLS staff can delete files. If you need a file deleted, contact researchprograms@lls.org for assistance.

Once the deadline has passed, only the following updates may be made:

- Regulatory approvals
- Significant updates to clinical trials:
  - IRB updates
  - Opening of the trial
  - Patient enrollment
  - Opening of new clinical sites
  - Efficacy and/or safety updates
- Updates regarding any transfers to a new institution

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