THE INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER (IASLC)

REQUEST FOR PROPOSAL (RFP)

TO PROVIDE

Statistical Management Services for the 10th Edition of the IASLC International Staging Project – Lung Cancer, Mesothelioma, Thymic Malignancies

CASEY CONNOLLY, MPH
PROJECT MANAGER, SCIENTIFIC AFFAIRS
Revised: 12.18.2023
1. Program Description

1.1 Overview
The International Association for the Study of Lung Cancer (IASLC) stands at the forefront of global efforts to conquer thoracic malignancies in the 21st Century. As a dedicated organization committed to advancing the understanding and management of these diseases, the IASLC has been responsible for the development and continual refinement of the TNM Staging Classification system for lung cancer, mesothelioma, and thymic tumors, that serves as a cornerstone in the assessment, diagnosis, and treatment planning for patients worldwide since 2009. We have produced the 7th, 8th and most recently the 9th editions of the staging classification system.

With a legacy of pioneering research and innovation, the IASLC proudly announces its endeavor to create the 10th edition of the IASLC International TNM Staging Project. This monumental undertaking represents a critical step towards further enhancing the precision and clinical utility of the tumor, node, metastasis (TNM) staging system, ensuring that healthcare professionals can provide the most accurate prognostic and therapeutic guidance to patients.

Staging lung cancer and other thoracic malignancies accurately is critical in deciding treatment regimens and ensures best standardized care for patients worldwide. The 10th edition seeks to expand our data elements to align with emerging biomarker and low dose CT (computed tomography) data. Such enhancements to the system may significantly improve the current anatomic staging system leading to more precise treatment decisions and improved patient survival.

To achieve our goal, the IASLC is seeking a dedicated and highly qualified statistical management partner with a proven track record in the field of oncology and staging system development. We invite you to submit a proposal to partner with us in this venture, contributing your expertise to the comprehensive analysis, data management, and statistical modeling necessary for the creation of the 10th edition of the IASLC International TNM Staging Project.

This Request for Proposal (RFP) outlines our expectations, objectives, and specific requirements for the statistical management of this project. As we embark on this journey to refine the staging of lung cancer, mesothelioma, and thymic tumors, we look forward to collaborating with an organization that shares our passion for advancing oncology and ultimately improving the lives of countless patients.
2. Goals, Objectives and Deliverables

2.1 Goals
The goal of this 7 year IASLC 10th edition staging project is to update and refine the lung, mesothelioma and thymic staging systems in a clinically relevant manner to assist physicians and patients in determining and executing their optimal treatment program.

2.2 Objectives
The IASLC staging project aims to:

1) acquire complete clinical and pathological data from over 100,000 thousand patients across the world diagnosed with all stages of lung cancer, mesothelioma and thymic carcinoma for survival analysis
2) acquire complete clinical and pathological data from over 100,000 thousand patients across the world diagnosed with all stages of lung cancer, mesothelioma and thymic carcinoma for prognostication.
3) determine if revisions to any of the TNM staging components and the overall stage of disease needs modifications from the 9th edition.
4) timely and worldwide presentations and publications of the data.
5) identify and prioritize secondary exploratory analysis

To accomplish our goals, the IASLC is seeking a statistical center partner who has a proven record of creating, executing and monitoring large databases and performing advanced statistical analyses of these big datasets to draw clinically relevant conclusions.

2.2 Deliverables

- Development, deployment, and maintenance of a high quality and robust Electronic Data Capture (EDC) system.
- Timely completion of all analyses for the core publications as determined by the staging project team and outlined in the protocol. The protocol will be developed in collaboration with the staging project team and the selected statistical center.
- Generate all figures, tables and methodology sections for presentations and publications.
- Attend and provide input in required virtual and/or inperson meetings.
- Generate monthly reports on data quality and accrual for each of the disease categories.
- Provide and adhere to the budget.
- Generate quarterly budget reports and attend the budget meetings.
- Attend and prepare analyses and presentations for a yearly meeting with the staging project team.
3. Proposal Timeline

3.1 Proposal Submission

Statistical centers must send proposals and inquiries related to this RFP via e-mail, on or prior to March 1, 2024, by 11:59pm MST to casey.connolly@iaslc.org.

Each proposal should provide a straightforward, concise description of the center’s ability to meet the requirements of this RFP. Proposals should not contain unsolicited, extraneous, or duplicative information. Proposals must be based solely on the requirements contained in this RFP.

By submitting a proposal, the statistical center grants the IASLC the right to obtain any information from any lawful source regarding the history, practices, conduct, and ability of Agency to perform the services and otherwise to fulfill the requirements under this RFP, and the history, practices, conduct, and ability of any director, officer, or key employee of Agency.

3.2 RFP Schedule

<table>
<thead>
<tr>
<th>Table 1: RFP Schedule</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribute RFP</td>
<td>1/5/24</td>
</tr>
<tr>
<td>Submission Deadline</td>
<td>3/1/24</td>
</tr>
<tr>
<td>Evaluate vendor proposals</td>
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</tr>
<tr>
<td>Notification of Selection</td>
<td>3/25/2024</td>
</tr>
<tr>
<td>Anticipated Period of Performance</td>
<td>10/1/2024-12/31/2031</td>
</tr>
</tbody>
</table>

4. Background Information

4.1. TNM Staging Classification System

The TNM Staging Classification system is a fundamental tool in the assessment and treatment of lung cancer, and other thoracic malignancies, providing healthcare professionals with a standardized and comprehensive method for categorizing the extent of disease, guiding treatment decisions, and predicting patient outcomes. The staging system is updated every 10 years. The IASLC has played a pivotal role in the development and continuous refinement of this staging system, acknowledging its significance in the fight against lung cancer.

Understanding TNM Staging:
- T (Tumor): This component describes the size and extent of the primary tumor.
- N (Nodes): The N category evaluates the extent of regional lymph node involvement.
- M (Metastasis): The M component identifies whether the cancer has metastasized, or spread to distant sites, in the body.

Significance of TNM Staging in Treatment of Lung Cancer, Mesothelioma, and Thymic Maligancies:
• Treatment Guidance: Accurate TNM staging is pivotal in guiding the choice of treatment for patients with lung cancer. Early-stage disease (Stage I and Stage II) is often amenable to curative surgical resection, while advanced-stage disease (Stage III and Stage IV) may require multimodal approaches, including surgery, radiation therapy, chemotherapy, targeted therapies, immunotherapies, or a combination thereof.

• Prognostic Information: The TNM stage provides crucial prognostic information, helping clinicians and patients understand the likely course of the disease. It allows for a more informed discussion of potential outcomes and helps patients and their healthcare teams make treatment decisions that align with individual goals and expectations.

• Research and Clinical Trials: The TNM staging system is integral to research and the development of clinical trials in the field of thoracic malignancies. It allows for the selection of patients with similar disease stages and characteristics, ensuring the validity of study results and the ability to develop more effective treatments.

• International Consistency: The IASLC’s efforts in refining the TNM staging system promote international consistency in lung cancer, Mesothelioma, and Thymic malignancy classification. This ensures that healthcare professionals around the world use a common language to describe and treat thoracic malignancies, facilitating collaboration and the exchange of knowledge in the global fight against these diseases.

The launch of the 10th Edition of the IASLC International TNM Staging Project demonstrates the IASLC’s ongoing commitment to improve the precision and clinical utility of the staging system, which helps healthcare professionals make informed decisions, ultimately improving patient outcomes and quality of life.

4.2. 9th edition TNM staging system

The IASLC is set to complete all work related to the 9th edition of the staging project by the end of 2024. The 9th edition database for lung cancer included 124,581 globally distributed cases from over 100 sites. Following data quality checks by our current statistical manager a total of 87,043 cases were used in the analyses to inform the changes to the lung cancer staging classification. The 9th edition Thymic database included 11,347 cases that were used for analysis and the Mesothelioma database has a total of 3,481 cases that were analyzed. Table 2 lists all the core manuscripts. A similar set of publications is anticipated for the 10th edition. Additional statistical support for secondary analyses and publications from members of the staging project team requires review and approval of the project steering committee in conjunction with the statistical center. There are plans to conduct biomarker analyses for lung and mesothelioma.

<table>
<thead>
<tr>
<th>Disease Category</th>
<th>Manuscript</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung Cancer</td>
<td>Database Overview</td>
</tr>
<tr>
<td></td>
<td>T Category</td>
</tr>
<tr>
<td></td>
<td>N Category</td>
</tr>
</tbody>
</table>
5. Specific Requirements

5.1 Program Management

- Scheduling routine teleconference calls.
- Agenda and Meeting minutes for joint teleconference calls.
- Compiling detailed summaries for work completed each month to include in each invoice.
- Managing site permissions.
- Coordinating legal agreement (DUA, Service Agreements, others) negotiations in collaboration with IASLC staff.
- Work in collaboration with IASLC staff and members of the staging project team to develop an effective site onboarding process including data submission tutorials, tool kits, and being available to assist sites on an individual basis.

5.2 Electronic Data Capture (EDC) System Development

- Develop a HIPPA and GDPR compliant electronic data capture (EDC) system to collect pseudonymized datasets from approximately 50-100 global institutions.
- Work in collaboration with the members of the IASLC Staging Project Team, including a global and multidisciplinary cohort of 80 thoracic researchers and IASLC staff to develop an EDC containing all the data elements in the appendices (Please see section 5).
- Provide statistics knowledge throughout the EDC development phase.
- Develop the EDC on time and on budget.
- Update the data elements in the EDC as necessary as the study evolves.
- Train all IASLC staff working on project and project leadership on the basic functions of the EDC.
• Successfully manage the transfer of all historical data
  • **Database Features**
    • Intuitive user interface
    • HIPPA/GDPR compliant security features
    • Standardized reporting capabilities that can easily be generated upon request
    • Edit check capabilities to for data quality assurance, quality control
    • Electronic medical record (EMR) direct data transfer capabilities (not required, but preferred)
    • Incorporation of robust list of molecular data elements

5.3 Data Collection
• Develop an onboarding process in collaboration with the IASLC project manager assigned to this project.
• Provide support to sites and investigators throughout the data collection process.
• Collect and store all data transferred by sites in accordance with national and global data protection laws, including HIPAA and GDPR.
• Ensure all data collected is complete and includes all necessary data elements to complete analysis.
• Assist sites if any issues arise during the data collections process.

5.4 Statistical Support
• Assist with onboarding new sites that are contributing data from a study.
• Provide statistical support though answering any questions from sites, principal investigators, or other relevant stakeholders.
• Maintain a working database and troubleshoot any technical issues that may arise.
• Monitor EDC-submitted data and map/recode relevant non-EDC submitted data (batch data) to combine both data sources in analysis. *Batch datasets submission will be limited to sites who receive prior approval by the SPFC Steering Committee.
• Map biomarker data to consistent structure and merge biomarker data to clinical database.
• Generate interim status reports on ongoing data collection and completeness of data
• Provide statistical support and generate analyses of the submitted data for nineteen (19) subcommittees
  • 17 subcommittees for Lung cancer including but not limited to the following sub-groups: R-Factor, Validation and Methodology, Ground-glass opacity/ Adenocarcinoma in situ, and Prognostic Factors
  • One subcommittee for thymic
  • One subcommittee for mesothelioma

5.5 Statistical Analysis
• Analyze lung cancer, mesothelioma, and thymic malignancy data using sophisticated techniques to support recommendations for 10th Edition staging.
• Generate analyses, tables, figures, and Kaplan Meier curves for each of the subcommittees to support recommendation generation and ultimately publications and presentations.

5.6 Publications & Presentations
• Compile data and perform analysis to support any and all publications that result from this project with a
primary focus on the core T, N, M, Database Overview, Molecular and Stage publications for the lung cancer, mesothelioma, and thymic domains.

- Provide statistical support for complimentary analyses and publications outside of the core manuscripts that are approved by the project steering committee. Please note, complimentary publications will undergo a formal application and approval process and must provide additional funding to cover the proposed analyses.
- Compile data, perform analysis, and prepare slides for any presentations that result from this project.

### 6. Key Outputs and Timeline

The following table lists high-level outputs associated with the required scope of work for the contract. The applicant will also be responsible for the milestones and timelines it submits as part of their proposal. The applicant should assess the below timeline and propose modifications based on its own subject-matter expertise.

<table>
<thead>
<tr>
<th>Table 3: Key Milestones</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful transfer of historical data ensuring that patient data is protected according to HIPPA and GDPR regulations</td>
<td>Year 1</td>
</tr>
<tr>
<td>Work with IASLC staff to develop new protocols for the three disease categories</td>
<td>Year 1</td>
</tr>
<tr>
<td>Work with project committee to finalize data dictionary for all disease categories for the 10th edition</td>
<td>Year 1</td>
</tr>
<tr>
<td>Develop, launch, and test EDC</td>
<td>Year 2</td>
</tr>
<tr>
<td>Data collection for the 10th edition</td>
<td>Year 2-4</td>
</tr>
<tr>
<td>Close EDC</td>
<td>Year 4</td>
</tr>
<tr>
<td>Data Cleaning and Statistical Analyses</td>
<td>Year 4-6</td>
</tr>
<tr>
<td>Write core manuscripts</td>
<td>Year 5-7</td>
</tr>
<tr>
<td>Submit proposed changes to the staging classifications to UICC and AJCC for approval</td>
<td>Year 7</td>
</tr>
</tbody>
</table>

### 7. Award Information

#### 7.1 Award Amount

One 7-year contract will be awarded as a result of this RFP process. The award amount will be determined by the applicant and the IASLC. Note: As a nonprofit organization we have a policy cap of 25% for indirect costs. Salaries will be calculated on an FTE model.

#### 7.1 Eligibility Requirements

In order to be considered the Center must be an independent or academic health system associated statistical center with expertise in cancer and large data sets. Experience with cancer staging systems is not required but would be preferred. Experience utilizing Artificial Intelligence and Machine Learning technologies is preferred, but not required.
7.2 Period of Performance

<table>
<thead>
<tr>
<th>Table 4: Period of Performance</th>
<th>Date</th>
</tr>
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<tbody>
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</table>

7.3 Termination of Award
Funding is dependent on satisfactory performance against the scope of work and outputs and a decision that continued funding is in the best interest of the IASLC. Proposals will be funded subject to meeting terms and conditions specified in the resulting Contract and available funds. Awards may be terminated if these terms and conditions are not met. IASLC reserves the right to terminate the Contract for any reason.

8. Applications Details

8.1 Submission Instructions
This Request for Proposals serves as the application package and contains all the instructions to enable a potential applicant to apply.

8.1.1 Respondents Questions
IASLC encourages Respondents to submit questions by email (to casey.connolly@iaslc.org) seeking clarification of the RFP requirements. Questions will be reviewed on an ongoing basis and responses will be sent within 5 business days of receipt.

8.1.2 Submission Requirements
The proposal must be submitted to casey.connolly@iaslc.org no later than the established deadline listed in Table 1. All documents should be submitted as PDFs, including the proposed budget, which should be submitted using the provided budget template. A complete proposal will include: Title Page, Transmittal Letter, Abstract, Project Narrative, Qualification and Project Management, Budget and Budget Narrative.

8.1.3 Format Requirements
To ensure readability by reviewers, fairness in the review process, and consistency among applications, each application must follow the following specifications to be reviewed:
- Use 8.5" x 11" letter-size pages with 1" margins (top, bottom, and sides).
- All pages of the Response must be paginated in a single sequence.
- Font size must be no smaller than 12-point
- Follow the page limits as detailed in the next section

8.2 Application Content

I. Title Page (Attachment 1)
II. Transmittal letter (No more than 1 page single-spaced)
   1. Brief statement outlining experience and qualifications to undertake this project;
   2. A statement that all information in the response, including cost, shall remain valid during the review period.

III. Abstract (1 page single spaced)
   1. A succinct description of the proposal, how the funds will be used, and the impact of your services.

IV. Project Narrative (maximum of 3 pages single-spaced)
The Project Narrative should address how the Respondent will carry out the required service components. The Respondent should organize the narrative in the following bolded sections:
   1. Overall Project
      a. Describe the respondent’s overall approach to the project and management philosophy.
      b. How would the respondent organize and manage the work laid out in the RFP.
   2. Statistical Management Plan
      a. Describe the Respondent’s strategy for delivering on each of the objectives outlined in Section 3, Required Service Components and Scope of Work.
      b. Describe the activities the Respondent will undertake to complete the scope of work.
      c. Describe the tools, methods, and subject matter expertise that will be leveraged.
      d. Implementation timeline
   3. Impact on Project Goals
      a. Describe how the respondent will ensure all project goals and objectives are met.
      b. Describe why the respondent is the best fit for this contract.

V. Qualification and Project Management (maximum of 3 pages single-spaced)
This section should describe the background and experience of the Respondent necessary to carry out this project. The Respondent should organize the narrative in the following bolded sections:
   1. Qualifications and Experience
      a. Describe the Respondent’s overall qualifications and background to carry out a project of this nature and scope. Should include its experience in implementing a similar initiative with other organizations.
      b. Describe the Respondent’s content level knowledge relevant to the scope of work with the proposed services outlined in Section 3. Required Service Components and Scope of Work.
      c. Describe contracts held within the past five years with a scope similar to this one. What did you learn from your successes and failures that you would apply here?
   2. Organizational and Project Structure
      a. Provide an organizational structure of the statistical center indicating lines of authority and detail how this proposed project structure fits within the larger structure of the organization.
      b. Describe how the project structure will enable effective implementation.
   3. Project Management
      a. Explain the staffing and management model of the organization as well as for the specific team who would be working with the IASLC.
         i. Please note, IASLC must approve all additional staff added to the project following award acceptance.
      b. Detail the names of proposed personnel, their proposed role, expertise, functions and time commitments.
      c. Include the name of a Project Manager who will serve as a single point of contact for the implementation of the project and who will be available to provide status updates and attend all project meetings at the request of IASLC.
   4. Resumes
a. Attach resumes for each proposed personnel. The resume shall include contract-related experience, credentials, education, training, and work experience.

5. Project Plan and Timeline
   a. Provide a project plan and timeline for completing proposed deliverables. Provide key activities and outputs, beginning and end dates for each, and the accountable person.

VI. Budget and Budget Narrative (Attachment 2) (Please submit budget using the provided budget template)
   a. Identify all proposed personnel with a corresponding total salary requested based on the full time equivalent (FTE) rate. Estimate the total hours expended for the project, broken down by the following categories:
      a. Statistical Support
      b. Project Management
      c. Legal/Executive Oversight
   b. Identify at the granular level detail all the one-time and recurring costs relate to building and maintaining the Electronic Data Capture (EDC) system
   c. Identify travel costs separately.
   d. Provide a narrative explanation to support the proposed budget based on the template in Attachment 2.
   e. Include a total budget proposal for Years 1-7 of the project.
   f. Budget and budget narrative should follow the template provided in attachment 2.
   g. Indirects capped at 25%

9. Evaluation and Selection
This section describes the evaluation criteria for this RFP. The review criteria are based on a total of 100 points allocated across the Project Narrative (50 points), Qualifications and Project Management (30 points), and the Budget Narrative (20 points).

Table 6: Evaluation Criteria

<table>
<thead>
<tr>
<th>Application Package</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title Page</td>
<td>Required</td>
</tr>
<tr>
<td>Transmittal Letter</td>
<td>Required</td>
</tr>
<tr>
<td>Abstract</td>
<td>Required</td>
</tr>
<tr>
<td>Project Narrative</td>
<td>50</td>
</tr>
<tr>
<td>Qualifications &amp; Project Management</td>
<td>30</td>
</tr>
<tr>
<td>Budget Narrative</td>
<td>20</td>
</tr>
<tr>
<td><strong>Total (100)</strong></td>
<td></td>
</tr>
</tbody>
</table>

9.1 Review and Selection Process
It is the intent of the IASLC to conduct a comprehensive, fair and impartial evaluation of the Responses received to this competitive procurement. Only those submissions found to be responsive to the RFP requirements will be evaluated and scored. A committee consisting of qualified experts from the IASLC Board of Directors, the Staging Project Team and independent statisticians will review the applications to assess the degree of responsiveness, and clarity in their plan to meet the project goals and milestones. The review process will include the following:

- To be considered for review, applications will first be screened for completeness and adherence to eligibility criteria.
The review panel will assess each application to determine the merits of the proposal. The IASLC reserves the right to request that Respondents revise or otherwise modify their proposals and budget based on IASLC recommendations.

- IASLC may elect to conduct interviews with the finalists prior to awarding the right to negotiate a contract. Any expenses incurred by the Respondent to participate in such interview shall be the responsibility of the Respondent.
- Final award decisions will be made by the IASLC Chief Executive Officer (CEO). In making these decisions, the CEO will take into consideration: recommendations of the review panel; the readiness of the applicant to complete the scope of work and objectives; and the reasonableness of the estimated budget.
- IASLC reserves the right to conduct negotiations with applicants upon receipt of their proposal.

9.2 Procurement Process

9.2.1 Contract Execution
The contract created from this RFP must follow IASLC standard procedures and all laws of the governing body. The contract becomes official when the CEO of IASLC and the Statistical Center signs it, and no financial commitments can be made until this approval occurs.

9.2.2 Acceptance of Content
If selected, the RFP and the winning Respondent's Response will shape the final contract. This contract will be a Service Agreement (SA) between the winning Respondent and IASLC. IASLC has the authority to make decisions regarding the interpretation of all terms and conditions.

9.2.3 Incurring Costs
The IASLC is not liable for any cost incurred by the Respondent prior to the effective date of a contract, including costs associated with preparation and submission of response to this RFP.

9.2.3 Key Personnel
IASLC has the right to approve or reject changes in key personnel, except for those who left the job. They also have the authority to approve new key personnel when replacements are needed. IASLC can demand that poorly performing key personnel are replaced, even if they were previously approved.
Attachment 1: Proposal Title Page
IASLC
Request for Proposal
10th Edition IASLC International Staging Project
Proposal Face Sheet

1. Responding Center

Legal Name: ______________________________________________________

Street Address: ____________________________________________________

Country: __________________________________________________________

Town/City/State/Zip: ______________________________________________

2. Director/CEO

Name: _____________________________________________________________

Title: ______________________________________________________________

Telephone: __________________________________________________________

Email: ______________________________________________________________

3. Contact Person

Name: ______________________________________________________________

Title: ______________________________________________________________

Telephone: __________________________________________________________

Email: ______________________________________________________________

Attachment 2: Budget Narrative Instructions
**Budget Narrative**

The respondent must submit a budget in accordance with the instructions provided in this document. Costs must be reasonable and aligned with the proposed project scope. Proposed cost of service will be evaluated as part of the overall proposal score.

The budget shall include a maximum cost for the contract period (broken down by Year) for the proposed services. Payment will be based on actual costs incurred not to exceed the Budget maximum for each budget category, and for the overall Budget.

Please use the budget template provided to develop a detailed budget proposal, proposals that do not use the budget template will not be evaluated. Please also include a budget summary table dividing the 7-year project budget into 3 project phases: start-up, data collection, data analysis. This summary table should include overall cost for each phase and personnel, fringe, travel, and supplies for each phase (See template table below). Please also include a budget justification for all costs listed in the budget template.

**Full Time Equivalent Budget Model (FTE Model)**

Total personnel salary (A) requested should be calculated using full time equivalent (FTE) calculation.

I. **Definition of FTE:** An FTE represents a standardized unit of measurement for human resources, equating to the work hours of a full-time employee. It is used to quantify the total work hours available within an organization, taking into account both full-time and part-time employees.

II. **Calculation of FTE:** To calculate FTE, you sum the total hours worked by full-time employees (usually 40 hours per week) and a portion of the hours worked by part-time employees. For example, if two part-time employees each work 20 hours a week, they would collectively represent one FTE (40 hours).

**Summary Table Template (Include for Start-Up, Data Collection, Data Analysis & Publications Phases)**

<table>
<thead>
<tr>
<th>Phase 1: Start-Up</th>
<th>Budget Category</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A. Personnel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>B. Fringe</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C. Supplies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D. Travel</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E. Other</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F. Total Direct Costs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>G. Total Indirect Costs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H. Total Budget</td>
<td></td>
</tr>
</tbody>
</table>

In addition to completing the attached budget template, please include a budget narrative
justification as follows:

A. Personnel – Salaries & Wages
For each requested personnel please provide the following information: name of staff (if available), job title, annual salary, fringe benefits, percentage of time budgeted for this project (FTE), and total salary requested. Also, provide a justification and describe the scope of responsibility for each position, relating it to the accomplishment of project goals.

Fringe Benefits
Fringe benefits are usually applicable to direct salaries and wages. Provide information on the rate of fringe benefits used and the basis for their calculation. If a fringe benefit rate is not used, itemize how the fringe benefit amount is computed (retirement, FICA, Insurance, Worker’s Compensation, etc). This can be done for all FTE in one table instead of itemizing per employee.

Sample Personel Budget (Yearly)

<table>
<thead>
<tr>
<th>Position</th>
<th>Annual Salary</th>
<th>Annual FTE</th>
<th>Fringe Benefits</th>
<th>Total Annual Salary Requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Manager, John Doe</td>
<td>$100,000</td>
<td>0.75</td>
<td>$12,000</td>
<td>$87,000</td>
</tr>
<tr>
<td>Sr. Biostatistician, (*Vacant)</td>
<td>$110,000</td>
<td>1.0</td>
<td>$18,000</td>
<td>$128,000</td>
</tr>
</tbody>
</table>

Sample Justification
The Project Manager will use 0.75 FTE to provide general project oversight, communicate with sites, act as the main point of contact between the IASLC and Center, organize all legal agreements, prepare slides for and run quarterly meetings project update meetings. The Sr. Biostatistician will be assigned a full FTE for this project and will be responsible for managing a team of statisticians, running internal stats meetings, writing code for the EDC, checking all work of all other statisticians on project, traveling to annual project meeting to present on behalf of the statistical center, and all other miscellaneous tasks as assigned.

B. Supplies
Individually list each item requested. Show the unit cost of each item, number needed, and total amount. Provide justification for each item and relate it to specific program objectives. If appropriate, General Office Supplies may be shown by an estimated amount per month times the number of months in the budget category.

Sample Supplies Budget (Yearly)

<table>
<thead>
<tr>
<th>Category</th>
<th>Units</th>
<th>Cost per Unit</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Office Supplies (12 months)</td>
<td>10 (staff)</td>
<td>$250</td>
<td>$2500</td>
</tr>
<tr>
<td>Laptops</td>
<td>3</td>
<td>$600</td>
<td>$1800</td>
</tr>
<tr>
<td>Software Licenses</td>
<td>10</td>
<td>$250</td>
<td>$2500</td>
</tr>
</tbody>
</table>

Sample Justification
General office supplies will be used by staff to complete daily activites related to the project. Three staff members will be given new laptops because their current laptops do not support the necessary software needed to complete the aims of the project. New software licenses will be given to all staff on project to ensure back-end access to the Electronic Data Capture system, this will allow our team to work seamlessly to troubleshoot problems and complete all project goals.
C. Travel
The IASLC anticipates the need for 1-2 statisticians from the Center to travel to the IASLC World Conference on Lung Cancer (WCLC) to attend the annual in-person meeting of the Staging and Prognostic Factor Team. WCLC rotates regionally between North America, Asia/Rest of World, and Europe each year. All travel will be booked in accordance with the IASLC travel policy, which will cover a roundtrip economy class ticket to WCLC and 2-3 nights of accommodation depending on meeting location. Total travel costs per year will not exceed $10,000.

Sample Travel Budget (Yearly)

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Annual Travel Requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jane Doe, Sr. Biostatistician</td>
<td>$5000</td>
</tr>
<tr>
<td>John Doe, Project Manager</td>
<td>$5000</td>
</tr>
<tr>
<td>Total Year 1 Travel</td>
<td>$10000</td>
</tr>
</tbody>
</table>

Sample Justification
Funds are being requested to offset the costs for the Center’s key statistical staff to travel to the annual Staging and Prognostic Factors Team meeting which occurs at WCLC.

The following budget for travel is requested:
Year 1: $10,000
It is estimated that the actual travel cost to the annual meeting in year 1 will be $5000 per person for the lowest cost airfare, hotels, meals, and incidental costs. Based on the IASLC travel policy, which will cover all travel costs for up to 2 key staff members to travel to WCLC, the maximum annual travel costs will be $10,000.

D. Other
This category contains items not included in the previous budget categories. Individually list each item requested and provide appropriate justification related to the program objectives.

E. Total Direct Costs
Show total direct costs by listing totals of categories A-E.

F. Total Indirect Costs
As a nonprofit organization we have a policy cap of 25% for indirect costs, respondents should use this policy to inform the submitted indirect costs rate.

G. Total Budget
Show total direct costs by listing totals of categories F & G.