LOA RESEARCH GRANT GUIDELINES

NOTE: Applications will be initially reviewed based on scientific merit and relevance to the LOA mission, alone. As such, reviewers will be blinded to the identity of the Principal Investigator (PI), collaborators, and their organizations. Applications that identify the PI, collaborators, or their organizations in the application will be rejected for noncompliance. Applications that are selected for second level review will be unblinded and the study team will be evaluated.

A document describing common blinding mistakes to avoid can be found on the eBRAP "Funding Opportunities & Forms" web page. (<u>https://ebrap.org/eBRAP/public/Program.htm</u>).

1. APPLICATION REQUIREMENTS

The grant application must be completed in full and submitted together with the components requested in these grant guidelines. Any application not completed in full or does not comply with formatting requirements will not be considered. The application must not identify the Principal Investigator (PI), collaborators, and their organizations. The complete application includes the following:

- Biographical Sketch (two pages maximum per investigator), CDMRP Format
- Technical Abstract (one page)
- Research Plan (four to six pages)
- References Cited (no page limit)
- Budget and Budget Justification (no page limit)
- Formatting (all documents):
- o 1-inch margins
- o 12-point Times New Roman font
- o Single spaced, left aligned paragraphs
 - 2. **DEADLINE FOR FINAL APPLICATION** You must complete your submission no later than January 10, 2025 at 11:59 CT for consideration of this grant opportunity.

3. APPLICATION PROCEDURES

Complete application components and combine all documents into two separate PDF files. One file should contain the Technical Abstract, Research Plan, References Cited, and the Budget and Budget Justification; this file should be titled: Last Name, FI_LOA Research Grant_2025_Scientific Evaluation. The second file should include the Biographical Sketch(es); this file should be titled: Last Name, FI_LOA Research Grant_2025_Personnel Evaluation. Once you have created the combined PDFs document, email the application as attachments to Karen Fernandez (kfernandez@datatrace.com).

4. APPLICATION COMPONENTS

<u>TECHNICAL ABSTRACT</u>: This is the summary of the application and summarizes the major areas of the application. **The technical abstract is limited to one page**. This should include the following:

- Alignment with the LOA Mission of helping to optimize orthopaedic care in the state of Louisiana: State how the proposed research fulfills/furthers the LOA Mission
- Background: Briefly states the salient background and gaps this grant addresses
- Objective/Specific Aims: This is the most important part of the application. List the broad, long-term objectives and the specific aims to be accomplished

<u>BIOGRAPHICAL SKETCH</u>: Download the blank Biographical Sketch form from the LOA website and complete using the instructions below. With your application, please include the biographical sketches of all KEY personnel including consultants.

The Biographical Sketch for each investigator is limited to two pages. In addition, please provide all current, past and pending research funding on the provided template.

<u>RESEARCH PLAN</u>: The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. No part of the application may identify the PI, collaborators, or their organizations. Concisely state the ideas and reasoning on which the proposed work is based. State the project's hypotheses, objectives, and specific aims, and succinctly but with sufficient detail describe the experimental approach. Be specific and informative and avoid redundancies. **The Research Plan has a limit of five pages (excluding the References Cited section).**

The Research Plan should answer these broad questions:

- What do you intend to do?
- Why is the work important?
- What has already been done?
- How are you going to do the work?

Organize the Research Plan in the order specified below and using the instructions provided below. Start each section with the appropriate section heading. Cite published experimental details in the Research Plan and provide the full reference in the References Cited section. If an applicant has multiple specific aims, then the applicant may address significance, innovation and approach for each specific aim individually, or may address significance, innovation and approach for all of the specific aims collectively.

- Background: Describe in detail the rationale for the study and include a literature review, preliminary studies, and preliminary data that led to the development of the proposed project. The Background section should clearly explain the basis for the study objectives and/or hypothesis and specific aims.
- 2. Relevance: Identify how the proposed work aligns with or advances LOA's mission. Explain the study's relevance to medicine optimization in the state of Louisiana.
 - Explain how the proposed project improves clinical decision to optimize orthopaedic care in Louisiana.
 - Describe the significance of the project's objective and/or subjective measures or metrics.

- 3. Objectives/Specific Aims/Hypotheses: Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- 4. Research Design and Methods:
 - Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation.
 - If applicable, describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives.
 - Document the availability and accessibility of the samples, data, and/or other materials/resources needed for the proposed research, as applicable.
 - Address potential problem areas and present alternative methods and approaches.
 - If applicable, describe the type of clinical trial (e.g., Phase/Class, prospective, randomized, controlled) or clinical research (i.e., observational studies to include correlative and epidemiological studies) to be performed. Outline the proposed methodology in sufficient detail to show a clear course of action.
 - If applicable, describe the intervention to be studied and the proposed indication. Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research, and describe how quality control will be addressed. Include a discussion of any current clinical use of the intervention, and/or details of its study in clinical trials for other indications.
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (i.e., convenience, simple random, stratified random). Specify the approximate number of human subjects that will be accrued. Address any potential barriers to human subjects accrual and plans for addressing potential delays.
 - Describe how the subject-to-group assignments process will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Include a discussion of risk/benefit considerations.
 - Data and Statistical Analysis Plan: Describe how data will be collected and analyzed in a manner that is consistent with the study objectives.
 - If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

- If applicable, specify the approximate number of human subjects/samples that will be accrued. If multiple study sites are involved, state the approximate number to be enrolled at each site.
- If applicable, describe how data will be reported and how the PI will assure that the documentation will support a regulatory filing with the FDA.

<u>REFERENCES CITE</u>D: List all references used in the Research Plan. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research. References and in-text citations should follow the American Medical Association citation format.

<u>BUDGE</u>T: Applicants are free to present their proposed budget in any format. Please list each major expense separately with a brief description and total amount. Supplies under \$200 do not need to be itemized.

- Financial Records: Separate accounts must be maintained for each grant. These accounts, with substantiating invoices and other expenditure data, must be available at all times to LOA representatives.
- Completed Grants: Any unexpended balances of \$100 or more at the scheduled conclusion, or other termination of any LOA grant must be refunded to LOA within sixty (60) days or by July 31 of the year the grant is ended, together with the final report of the grant fund expenditures.

<u>APPENDIX</u>: Applications may include the following materials in the appendix:

- o Surveys, questionnaires, data collection instruments, and clinical protocols
- Letters of support (optional)

5. FISCAL PROCEDURES AND POLICIES

Facilities to be provided by the grantee(s) or their parent institutions: Research grants are designed to serve as supplementary funding for meritorious projects initiated or contemplated by the grantee(s) and their parent institutions. Therefore, the grantee(s) and such institutions are expected to provide all the necessary basic facilities and services normally expected in professional environments qualified to undertake the research. LOA expects that the grantee(s) will have available, whether from their own resources, funds other than those assigned by LOA, or from their parent institutions the following, unless otherwise specifically agreed upon:

- 1. Laboratory space;
- 2. Maintenance services, including maintenance supplies and service contracts;
- 3. Telephone service, if needed;
- 4. Library services, including subscriptions to periodicals and the purchase of books;

5. Laboratory furniture;

6. Salaries of principal investigator or co-investigators, unless otherwise agreed upon;

- 7. Foreign and local travel expenses of personnel working under the LOA grant;
- 8. Society dues and memberships of personnel working under the LOA grant;
- 9. Workers' compensation, public liability or other hazard and special insurance;
- 10. Office equipment;
- 11. Employee group life, disability, medical expense or hospitalization insurance;
- 12. Audio/visual project support devices and items; and

13. Hospital bed expense, nursing or related services, even when used for research studies pertinent to the subject of the LOA research grant.

As a matter of policy, LOA grant funds may not be used to pay institutional overhead/indirect (facilities and administrative) expenses. The bulk of the grant should generally be dedicated to purchasing those materials that are directly related to completion of the project. The cost of disposable or non-reusable experimental equipment or costs for use of equipment in the institution are generally justified. The purpose of this grant is not to stock laboratory with relatively permanent equipment or to pay an outside institution to perform work of the experiment.

6. REPORTING

<u>Status Update Reports for those Receiving Grants</u>: All grant recipients are required to submit status updates to LOA every 6 months after official notification of their selection. Failure to report on the project within 1 year of the award date or 1 year from most recent status update report can lead to withdrawal of grant support. The status updates are reviewed by the LOA Research Committee to ensure adequate progress towards the completion of the projects specific aims. If the project is adequately progressing, the next disbursement of grant funds will be made. Funds are equally disbursed based on the project timeline in the grant application. For any funded grant project to be considered complete, the recipient must provide a final report to LOA within the project period. No-cost-extensions (NCE) are considered on a case-by-case basis.

<u>Final Reports for Those Receiving Grants</u>: At the end of the funded study, the grantee(s) must prepare, sign (together with the countersignature of the responsible financial official of the parent institution where appropriate), and submit to the LOA a report of grant expenditures. A final narrative report is also required at the completion of the study that summarizes research findings. Manuscripts under consideration for or accepted for publication are also acceptable as a final report.

<u>Presentation of Findings</u>: The grantee(s) must present the findings of the study at the LOA annual meeting within 1 year of completing the proposed work.

7. **MODIFICATIONS:** Grantee(s) must receive written permission from LOA prior to moving funds between budget categories, changing effective dates of the grant, or making any other desired modifications. Grantee(s) may terminate a grant prior to normal expiration by notifying the LOA in

writing and stating the reasons for termination. Unexpended funds must be returned to LOA within sixty (60) days, together with a final accounting of expenditures under the grant. LOA reserves the right to terminate the grant at any time upon three months written notice to the grantee(s).

8. **PUBLICATION**: The following acknowledgment must appear as a footnote on the first page of the manuscript or printed text: "SUPPORTED BY A GRANT FROM THE LOUISIANA ORTHOPAEDIC ASSOCIATION." The same credit line must be included when the grantee(s) presents a paper at a professional or scientific meeting based on a study funded by the LOA.

9. **OWNERSHIP OF EQUIPMENT**: Equipment purchased under LOA grants becomes the property of the parent institution of the grantee(s) or its associated facilities.

10. **CORRESPONDENCE** Any questions or requests should be directed to Karen Fernandez, Louisiana Orthopaedic Association, at <u>kfernandez@datatrace.com</u>.