

## **Clinical Science in Manual Therapy**

Applications to the Calendar Year 2024 Clinical Science in Manual Therapy Program are being solicited by the AAOMPT Foundation.

### **Research Award**

The Clinical Science in Manual Therapy award is intended to support clinically-focused research that serves to advance the practice and clinical implementation of manual therapies in addition to growing the base of high-quality evidence related to manual therapy.

For the purposes of this award, manual therapy is defined as using a hands-on approach with the intent to deliver a therapeutic effect (i.e. reduce pain, increase function) in a patient with a neuromusculoskeletal disorder. The focus is on changes in joint structure and/or function (directly or indirectly, such as those as a result of neurophysiologic changes), and would NOT include the use of any assistive devices or instruments (e.g. instrumented soft tissue devices, any form of needle insertion, cupping, etc. - the use of mobilization belts are acceptable).

To meet the intent of this award mechanism the proposal MUST specifically address one of the identified focus areas below, but any aspect of research relevant to these focus areas may be considered for funding.

1. Understand the influence of manual therapy dosing on clinical outcomes (specific to each single session as well as frequency and timing of visits over the course of care), to include variability and innovation in delivery mechanisms that optimize the effects of manual therapy.
2. Understand the role of manual therapy as an alternative to higher risk pain interventions (opioids, injections, invasive procedures), to include comparing influence on clinical outcomes and differences in treatment-related adverse effects and preventing escalation of mid to long-term health services and utilization of other higher-risk/more invasive treatments.
3. Understand the contextual factors that are associated with manual therapy utilization, perception and outcomes, from both patient and clinician perspectives.
4. Understand the comparative effectiveness of manual therapy against other common acute pain modalities.
5. Understand the influence of training, skill and advanced practice related to manual therapy on patient-centered outcomes of pain and physical function.

### **Potential designs include:**

- Studies that can adequately assess and identify responder status
- Studies that assess real-world barriers to implementation of manual therapy in clinical settings (patient perception, clinician perception, administrative barriers, economic barriers, etc.)
- Studies that explore and clearly define the extent to which manual therapy does or does not lead to patient dependency (physical, emotional, psychological) or changes in self-efficacy, or adversely affects patients' ability to otherwise properly self-manage.
- Pragmatic designs that allow for real-world implementation of manual therapy that accounts for patient and clinician preferences, variability in dosing of manual therapy, and combination of MT with other treatment based on patient/clinician preference.
- Trials that compare multiple approaches to the delivery and dosing of manual therapy
- Studies that compare the treatment effects of manual therapy across a variety of musculoskeletal disorders

- Studies that identify and validate outcomes that are sensitive enough to properly capture changes attributable to manual therapy, but also remain clinically relevant.

#### Letter of Intent (LOI) Components (Maximum of 3 pages)

- **Background (to include how it ties specifically to a Manual Therapy focus area listed in this RFP)**
- **Research Idea (includes aims and hypothesis)**
- **Research Strategy (to include study design)**
- **Key Personnel (biosketches - not part of 3-page limit)**
- **Impact and Relevance to Manual Therapy**

#### Full Grant Components:

##### **Project Narrative (12 page limit)**

- Background
- Objectives/Aims/Hypothesis
- Study Design
- Statistical Plan (includes appropriate sample size calculations)
- Relevance to Manual Therapy

##### **Technical Abstract (1 page limit)**

- Background
- Relevance to Focus Area
- Hypothesis/Objective/Aims
- Study Design
- Clinical Impact

##### **Intervention (if applicable; no page limit)**

- Description of Intervention
- Study Procedures (diagram, flowchart, etc.)
- Monitoring Plan

##### **Human Subject Recruitment and Safety Procedures (no page limit)**

- Study Population (table of anticipated enrollment)
- Screening criteria & Informed Consent Process
- Inclusion/exclusion criteria
- Recruitment Plan
- Risks and Benefits

##### **Transition Plan (1-page limit)**

- Summarize what will be needed to transition this work to the next level. How will this work result in establishing or reinforcing a relevant and sustainable line of work that supports what is needed to adequately address relevant manual therapy research gaps. What will necessary and relevant follow-on projects be after the completion of this work.

##### **Study Support (no page limit)**

- References cited
- Facilities, Equipment and Study Resources
- Letters of support and collaboration
- Intellectual Property (if relevant)

##### **Budget**

##### **Budget Justification**

##### **Technical Notes:**

Due to the relatively small size of this grant, indirect costs are not allowed. Please ensure your institution is aware.

Awardees are required to submit an annual progress report (template will be provided)

### LOI Screening Criteria

**Research Idea:** How well the scientific rationale is supported, and how well the background and availability of and accessibility to resources and subject population indicates the research is ready for the proposed study.

**Research Strategy:** How well the specific aims, patient population, and proposed methodology will address the hypothesis and/or reach the desired objectives.

**Personnel:** How the background and experience of the PI and other key personnel are appropriate to successfully complete the study.

**Impact and Relevance to Manual Therapy:** The degree to which the proposed study will address one of the specific Manual Therapy focus areas, and its relevance in advancing the discipline of manual therapy

### Full Proposal Screening Criteria

#### **Research Strategy**

How well the scientific rationale for clinically testing the intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/ preclinical evidence.

How well the study aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to answer clearly the clinical objective.

How well the inclusion criteria and subject-to-group assignment meet the needs of the proposed study.

How well the exclusion criteria are justified.

Whether the strategy of proposed enrollment is appropriate for the proposed research.

To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study.

#### **Intervention**

To what degree the intervention addresses the clinical need(s) described.

How the intervention compares with currently available interventions and/or standards of care.

How well research procedures are clearly delineated from routine clinical procedures.

The feasibility of delivering the intervention as proposed in the study.

#### **Recruitment, Accrual, and Feasibility**

How well the application addresses the availability of human subjects for the study and the prospect of their participation.

Whether the application demonstrates access to the proposed human subject population.

The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed study.

How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.

### **Clinical Impact**

How relevant the anticipated outcomes of the proposed study are to individuals affected by the specified disease/condition.

How well the sample population represents the targeted patient population that might benefit from the proposed intervention.

How the potential outcomes of the study will advance the clinical impact of manual therapy

### **Regulatory Strategy and Transition Plan**

How the regulatory strategy and development plan are appropriate and well described.

Is the proposed line of research that would ensue from this study appropriate and realistic?

Does the transition plan provide proposed next steps which appear reasonable, tangible, and appropriate for continuing this line of work?

Is there an appropriate plan for dissemination of study results and findings?

### **Statistical Plan**

To what degree the statistical model and data analysis plan are suitable for the planned study objectives.

How the statistical plan, including sample size projections and power analysis, is adequate to meet the objectives of the study and all proposed correlative studies.

Are primary and secondary outcomes clearly identified, with statistical approaches designated for each outcome and each aim?

### **Personnel and Communication**

Whether the composition of the study team (e.g., co-investigators, study coordinator, statistician) is appropriate.

To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the areas of study, and clinical studies in general).

How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.

How well the logistical aspects of the proposed study (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.

For multi-site clinical studies, how well the lead site responsibilities and human research protections regulatory coordination are defined and planned for.

### **Budget**

Whether the budget is appropriate for the proposed research.

**Scientific Review**

Letters of intent will be reviewed by members of the programmatic committee. The LOIs that are deemed to have met the intent of the award will be invited back for full proposals. Full proposals will then be sent out for scientific review by subject matter experts, where they will receive a scientific score based on the criteria listed above.

**Programmatic Review**

After the scientific review has been completed for all full proposals, the programmatic committee will convene to review all the proposals and identify proposals of the highest quality to recommend for funding. The goal will be to select the application(s) that best achieve the objectives of this Request for Proposals.

The following criteria will be used by programmatic reviewers to make the final decisions:

- 1) Ratings and evaluations of the peer reviewers
- 2) Relevance to the manual therapy research gaps and focus areas identified, as evidenced by the following:
  - a) Adherence to the intent of the award mechanism
  - b) Relative clinical impact