FLORIDA MEDICAL MALPRACTICE JOINT UNDERWRITING ASSOCIATION Request for Applications for Grants for Partnerships in Improving the Safety of Health Care Services (RFA # 2024-01) The Alvin E. Smith Safety of Health Care Services Grant Program

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SECTION 1: GENERAL INFORMATION

1.1 Background of the FMMJUA

The Florida Medical Malpractice Joint Underwriting Association ("FMMJUA") is a state-sanctioned insurance plan for medical malpractice coverage. The FMMJUA is an "insurance risk apportionment plan" created by section 627.351(4), Florida Statutes, for the purpose of assuring the availability of medical professional liability (malpractice) insurance to Florida health care providers. The FMMJUA provides medical professional liability insurance coverage in Florida for health care providers that cannot find coverage in the open market.

Responsibility for supervision of the FMMJUA is vested in a Board of Governors (the "Board") consisting of representatives from the Florida Medical Association, Florida Hospital Association, The Florida Bar, Florida Dental Association, and the insurance industry. Subject to the final approval of the Florida Office of Insurance Regulation, the Board approves insurance rates, rate classifications, policy forms, and otherwise sets the FMMJUA policy under the framework of the FMMJUA Plan of Operation. Operational and administrative functions are provided by a general manager and staff located in Tallahassee. The general manager is responsible for implementing policy and conducting the daily activities of the FMMJUA.

Customer service such as policy issuance, claims, and accounting is provided in the name of the FMMJUA by one or more eligible insurance companies (designated as servicing carrier) and sold by licensed general lines insurance agents. The Medical Protective Company is currently designated as the servicing carrier for the FMMJUA.

1.2 Objective

The number of patients in the United States and in the State of Florida harmed by the delivery of health care services is unacceptably high. With the approval of the Florida Office of Insurance Regulation, the FMMJUA intends to use a portion of surplus accrued from its operations to fund initiatives by Florida agencies or institutions to improve the safety of health care services by means of this request for applications ("RFA"). The ultimate goal of this grant program is to improve the safety of health care services for all Floridians. In this regard, the FMMJUA announces the availability of grants to improve the safety of the delivery of health care services to patients.

The purpose of this RFA is to support projects that are intended to (1) identify, develop, test, and implement safe practice initiatives in inpatient and/or outpatient settings; and (2) share the findings and lessons learned including the challenges and barriers to developing and implementing these interventions through validated tools, products, and/or health care safety toolkits. The interventions and any resulting implementation toolkits shall be made publicly available so that they may be adapted and/or adopted by other health care organizations.

1.3 Funds Available and Anticipated Number of Awards

The FMMJUA intends to commit up to \$5 million to fund the subject grants awarded under this RFA. The size of the awards may vary with the scope of the project proposed. However, the FMMJUA expects that most grant applicants will seek awards within the budget guidelines set forth in RFA Section 1.4 and that one or more new or extensions of existing projects will be funded via

this RFA. While the current financial plans of the FMMJUA provide support for this program, awards are contingent on the availability of funds and the receipt of a sufficient number of meritorious applications. The FMMJUA has the sole and absolute discretion to determine the number of grants to be awarded and reserves the right to award no grants.

1.4 Budget and Project Period

The total project period for an application submitted in response to this RFA may exceed one year. Applications must contain a separate budget for each project year. The total amount requested need not be the same in each year of a multi-year budget. As a guideline, the proposed budget for a project should limit total costs (direct and associated indirect costs) to \$1,000,000 over the entire project with no more than \$500,000 in total costs per year. However, an applicant may seek to justify a budget in excess of this guideline. Funding will be contingent upon a review and acceptance by the FMMJUA of a progress report every six months as described in the attached Grant Agreement. The FMMJUA may terminate a Grant Agreement for cause, for convenience, or when it determines that continuation of the Grant Agreement would not produce beneficial results commensurate with the further expenditure of funds as explained in the Grant Agreement.

It is anticipated that the project period will not exceed two years. However, an applicant may seek to justify a longer project period in their application. The FMMJUA may accept a longer project period if it determines in the FMMJUA's sole discretion that the additional time is warranted. If the FMMJUA awards a grant with a project period longer than two years, the Grant Agreement will be revised to reflect the additional time and progress reports will be required every six months for the duration of the project.

Applicants will be solely responsible for planning, directing and executing the proposed project. The FMMJUA's role will be to oversee and fund activities and projects intended to improve the safety of health care services undertaken by the selected agency or institution pursuant to this RFA.

1.5 Eligible Applicants

Any agency or institution located in Florida whose function includes activities intended to improve the safety of health care services is eligible to submit an application. Individuals are not eligible applicants under this RFA. An agency or institution that is currently receiving funds from the FMMJUA's Request for Applications for Grants in Partnerships in Improving the Safety of Health Care Services, RFA # 2013-01, or any grants thereafter, may apply to continue its current project for additional years or may submit an application for a new project. In either case, the agency or institution must fully complete this application. If the agency or institution is seeking additional years relating to a current project, the agency or institution must explain the benefit of continuing the project for additional years.

1.6 Eligible Principal Investigators

Eligible Principal Investigators ("PI") should be experienced senior level individuals familiar with patient safety and experienced in the development and implementation of interventions to improve the safety of health care practices and/or delivery, or have such substantial expertise available as part of the project team. The PI should devote a substantial portion of his/her time to the project and must be affiliated with the applicant.

1.7 Number of Applications

Each eligible agency or institution may submit one application in response to this RFA. Separate colleges within a single university are each considered an agency or institution. For example, the College of Medicine and the College of Nursing from the same university can both submit an application. In addition, separate colleges with separate campuses will also be considered an agency or institution. For example, the College of Nursing in Jacksonville and the College of Nursing in Gainesville of the same university can each submit an application. Other than universities, agencies or institutions will be considered separate rather than one and the same for purposes of this RFA if they have separate articles of incorporation, separate charters, and separate governing bodies. If the institution is a corporation, it must be registered as such and in good standing with the Florida Department of State, Division of Corporations, at the time of application, and remain in good standing during the course of the grant period.

1.8 Provider Organization

The applicant, or its partner(s), must be a health care provider organization capable of developing and implementing safe practice interventions in an inpatient or outpatient setting. Applicants that are not health care provider organizations must have a provider organization which is actively engaged in the delivery of health care as a participating partner in the proposed project. In such a case, the application must contain a memorandum of understanding ("MOU") or a letter of intent signed by the provider organization/participating partner specifying their commitment to the proposed project. If the applicant is awarded a grant and has submitted a letter of intent with its application instead of an MOU, the applicant will be required to submit an MOU prior to receiving its first funding disbursement. For purposes of this RFA, a health care provider organization is defined as an organization engaged in the direct delivery of health care services to patients in an inpatient or outpatient setting. Because the objective of this grant program is to improve the safety of health care services for Floridians, preference in the scoring may be given to applicants that propose partnerships with Florida-based health care providers that are treating Florida residents rather than partnerships with providers located outside of Florida.

1.9 RFA Timeline

The following timetable shows the approximate dates for this RFA process. The FMMJUA reserves the right to amend the timetable in its best interest at any time.

ACTION	DATE	LOCATION
Release of RFA	Tuesday, April 9, 2024	FMMJUA website
		www.fmmjua.com/fmmjua
Applicant Conference Call	Monday, April 29, 2024	Exact location and Dial-in
	2:00 p.m. EST	information will be posted on the
		FMMJUA website
		www.fmmjua.com/fmmjua
Deadline for Receipt of	Monday, May 6, 2024	Questions to be sent via email to
Written Questions	Received By 5:00	the following address:
Concerning RFA	p.m. EST	frankie@fmmjua.org

Response to Written Questions by FMMJUA	Monday, May 29, 2024	FMMJUA website www.fmmjua.com/fmmjua
Application Deadline	Wednesday, July 10, 2024 Received by 5:00 p.m. EST	FMMJUA 1836 Hermitage Blvd., Suite 201 Tallahassee, FL 32308-7704
Public Opening of Grant Applications	Monday, July 15, 2024 2:00 p.m. EST	FMMJUA 1836 Hermitage Blvd., Suite 201 Tallahassee, FL 32308-7704
Public Meeting of the Evaluation Team	October 22, 2024 FMMJUA Meeting	Exact time, location, and dial-in information will be posted on the FMMJUA website: www.fmmjua.com/fmmjua
Public Meeting of the Grant Committee	October 22, 2024 FMMJUA Meeting	Exact time, location, and dial-in information will be posted on the FMMJUA website: www.fmmjua.com/fmmjua
Oral Presentations (If Applicable)	January, 2025 FMMJUA Meeting Tallahassee, FL and/or Zoom option	Exact date, time, location, and dial-in information will be posted on the FMMJUA website: www.fmmjua.com/fmmjua
Public Meeting of the Grant Committee	February 6, 2025 FMMJUA Meeting	Exact time, location, and dial-in information will be posted on the FMMJUA website: www.fmmjua.com/fmmjua
Public Meeting of the FMMJUA Board	February 7, 2025 FMMJUA Meeting	Exact time, location, and dial-in information will be posted on the FMMJUA website: www.fmmjua.com/fmmjua
Posting of Grant Decision	+ 10 days approximately	FMMJUA website www.fmmjua.com/fmmjua
Earliest Anticipated Start Date	+ 2 weeks approximately	

1.10 Amendments

The FMMJUA reserves the right to amend this RFA at any time prior to the application submission deadline. Amendments will be issued as addenda to the RFA and posted on the FMMJUA website at https://www.fmmjua.com/fmmjua. It is the prospective applicant's responsibility to check the FMMJUA website periodically for any information or updates relating to this RFA.

SECTION 2: SPECIAL CONDITIONS

2.1 Inquiries, Contact with the FMMJUA

Except as otherwise permitted in Section 2.2 (Applicant Conference Call), the FMMJUA's exclusive contact person for this RFA is the FMMJUA General Manager, whose contact information is as follows:

General Manager **FMMJUA** 1836 Hermitage Blvd., Suite 201 Tallahassee, Florida 32308-7704 Fax: (850) 385-7126

E-mail: frankie@fmmjua.org

Questions or requests for clarification of any part of this RFA made outside of the Applicant Conference Call must be received in writing by the FMMJUA General Manager by the date and time specified in the RFA Timeline (Section 1.9). Inquiries must identify the organization submitting the inquiry and shall be submitted electronically as a Word document attached to an email sent to the FMMJUA General Manager at the email address indicated above.

NO TELEPHONE CALLS WILL BE ACCEPTED.

Responses to all inquiries will be posted on the FMMJUA website as an addendum to the RFA. The FMMJUA will not consider inquiries received after the deadline specified in the RFA Timeline (Section 1.9).

From the date this RFA is issued until a determination is made by the FMMJUA, all contacts or communications relating to this RFA between a prospective applicant (or any of the applicant's employees, agents, officers or directors) and the FMMJUA (or any of the FMMJUA's employees, agents, officers, evaluators, committee members or Board members) are prohibited, with the exception of contacts or communications authorized by this section or by Section 2.2 (Applicant Conference Call). Any unauthorized contact may disqualify the applicant from further consideration.

The only official position of the FMMJUA relating to this RFA is that position which is stated in this RFA and any addenda and the written answers to questions, which will be posted on the FMMJUA website. No other means of communication, whether oral or written, shall be construed as a formal or official response. Applicants should not rely upon any other communication.

2.2 Applicant Conference Call

The FMMJUA will hold an Applicant Conference Call on the date and time shown in Section 1.9 (RFA Timeline). The purpose of the conference call is to discuss the contents of the RFA and provide informal answers to questions from potential applicants. Participation in this conference call is not mandatory. The FMMJUA will accept oral questions during the conference and make a reasonable effort to provide answers at that time; however, oral answers and discussions are not binding. Only written responses to applicant questions are binding upon the FMMJUA.

Impromptu questions will be permitted and spontaneous answers provided at the FMMJUA's discretion. Verbal answers at the Applicant Conference Call are only intended for general direction and do not represent the FMMJUA's final position. Official answers will be posted on the FMMJUA's website. All oral questions must be submitted in writing via email following the close of the Applicant Conference Call, but no later than the deadline for written questions specified in Section 1.9 (RFA Timeline).

2.3 Cost of Application Preparation

The costs related to the development and submission of an application are fully the responsibility of the applicants and not chargeable to the FMMJUA.

2.4 <u>Disposition of Applications</u>

All applications become the property of the FMMJUA and will be a matter of public record subject to the provisions of Chapter 119, Florida Statutes.

2.5 <u>Certifications</u>

In submitting an application, an applicant certifies, represents and acknowledges the following (if an applicant cannot so certify any of the following, the applicant shall submit with its response a written explanation of why it cannot do so):

- (a) No Board member, official or employee of the FMMJUA has or will benefit financially or materially from approval of the application. Any grant or contract arising from this process may be terminated by the FMMJUA if it is determined that gratuities of any kind were either offered to or received by any of the aforementioned FMMJUA Board members, officials or employees.
- (b) Neither the applicant nor any person associated with the applicant who is or will be responsible for the administration of grant funds (including, but not limited to, any owner, partner, director, officer, principal investigator, project director, manager, auditor or other key personnel of the applicant) has within the preceding three years:
 - 1. been convicted of or had a civil judgment rendered against them or is presently indicted for or otherwise criminally or civilly charged for any of the following: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a federal, state, or local government transaction, public contract, or grant; violation of federal or state antitrust statutes; or commission of fraud, embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property; or
 - 2. had one or more federal, state, or local government contracts or grants terminated for cause or default.

2.6 Conflict of Interest and Disclosure

Applicants **must** disclose in their applications any officer, director, owner, employee, or agent of the applicant who is also an FMMJUA employee, agent, officer, committee, or Board member. Applicants must also disclose any FMMJUA employee, agent, officer, committee, or Board member who owns, directly or indirectly, an interest of five percent or more in the applicant or its affiliates. In the event that it is determined that the information in this section was not disclosed by the applicant in its application, the applicant will be disqualified and the applicant would give rise to an impermissible conflict of interest or otherwise be in violation of Florida law, the applicant will be disqualified and the application rejected.

2.7 Public Access to Records

Unless exempt by law, all documents, papers, letters, electronic transmissions, or other materials that are made or received by the selected agency or institution in connection with the grant or contract may be subject to the Public Records Law pursuant to Chapter 119, Florida Statutes.

All documents, papers, letters, electronic transmissions, or other materials that are made or received by the selected agency or institution in connection with the grant or contract shall be maintained for a period of five years after the expiration of the grant period. The FMMJUA may cancel the grant or contract in the event of a selected agency or institution's refusal to allow access to public records in accordance with Chapter 119, Florida Statutes.

If an applicant considers any portion of documents, data or records submitted in its application to be trade secret and exempt from public record disclosure, the applicant must clearly mark the information as "Trade Secret Material" and submit a separate redacted electronic copy of its application along with the original application. The first page of the redacted copy and each page on which information is redacted shall display the phrase "Redacted Copy." Failure to mark any portion of the application as trade secret waives the exemption for that portion.

The FMMJUA is not obligated to agree with an applicant's claim of exemption and, by submitting an application, applicant agrees to defend its claim that each of the redactions is exempt from inspection and copying under Florida's Public Records Law.

2.8 Intellectual Property

Grantees may copyright or seek patents for, as appropriate, final and interim products and materials developed in whole or in part with FMMJUA funds, including, but not limited to, methodological tools, measures, software with documentation, literature searches, and analyses. Such copyrights and patents are subject to a worldwide irrevocable FMMJUA license to use and permit others to use these products and materials for FMMJUA purposes, which may include making project materials, databases, results, and algorithms available for verification or replication by other researchers. In addition, final products may be made available to the health care community and the public by the FMMJUA or its agents if such distribution would significantly increase access to a product and thereby produce substantial or valuable public health benefits.

2.9 Right to Inspect, Investigate and Rely on Information

The FMMJUA may inspect an applicant's facilities and operations, investigate an applicant's representations, and rely on information about an applicant in the FMMJUA's records or known to its personnel in determining who shall be awarded a grant.

2.10 Special Accommodations

Any person requiring a special accommodation at a conference call or meeting of the FMMJUA because of a disability should contact the FMMJUA General Manager, at 850-385-8114 at least 48 hours prior to the conference or meeting, notwithstanding the prohibition contained in section 2.1 herein.

2.11 Public Bidding Requirements Inapplicable

The public bidding requirements under Chapter 287, Florida Statutes, are inapplicable to this RFA and no such bidding requirements are incorporated by this RFA. Nor does this RFA afford any formal protest rights under Section 120.57, Florida Statutes.

2.12 Grant Agreement

Appendix D contains the Grant Agreement that the parties will execute if a grant is awarded. The FMMJUA does not anticipate altering this agreement, but reserves the right to do so. An applicant that objects to a provision in the agreement must follow the procedure described in section 3.2(a) or the Applicant waives such objection.

SECTION 3: APPLICATION SUBMISSION INSTRUCTIONS

3.1 Application Receipt Deadline

All applications must be received no later than 5:00 p.m. (EST) on the date listed in the RFA Timeline (Section 1.9):

Florida Medical Malpractice Joint Underwriting Association 1836 Hermitage Blvd., Suite 201 Tallahassee, Florida 32308-7704

APPLICATIONS RECEIVED AFTER THE DATE AND TIME SPECIFIED ABOVE WILL NOT BE REVIEWED.

3.2 Content and Form of Application Submission

A complete application must include the original, four hard copies, and an electronic copy (on a USB flash drive in Adobe Acrobat format) of the items listed below, in the order outlined below.

(a) Completed and Signed Coversheet (Appendix A)

THE SIGNATURE ON THIS FORM CONSTITUTES ACCEPTANCE OF ALL

THE TERMS STATED IN THIS RFA AND ANY ADDENDA THERETO. THE SIGNATORY MUST THEREFORE BE A REPRESENTATIVE OF THE APPLICANT WITH THE AUTHORITY TO ACCEPT SUCH CONDITIONS ON BEHALF OF THE APPLICANT. IF THE COVERSHEET IS NOT SIGNED BY AN AUTHORIZED REPRESENTATIVE, THE APPLICATION WILL NOT BE REVIEWED.

(b) Completed and Signed "Acceptance of Grant Agreement" Form (Appendix B)

THE SIGNATURE ON THIS FORM CONSTITUTES ACCEPTANCE OF THE TERMS STATED IN THE GRANT AGREEMENT. THE SIGNATORY MUST BE A REPRESENTATIVE OF THE APPLICANT WITH THE AUTHORITY TO ACCEPT SUCH CONDITIONS ON BEHALF OF THE APPLICANT. IF THE ACCEPTANCE OF GRANT AGREEMENT FORM IS NOT SIGNED BY AN AUTHORIZED REPRESENTATIVE, THE APPLICATION WILL NOT BE REVIEWED.

If the applicant objects to any of the provisions in the Grant Agreement, the applicant must make a list of the terms that it objects to and provide alternative language. The FMMJUA may, in its sole discretion, amend the Grant Agreement if it is in the FMMJUA's best interests. By signing the Acceptance of the Grant Agreement form, the applicant agrees to be bound by the language in the Grant Agreement, even if FMMJUA chooses not to amend the language based on the applicant's objection.

- (c) A one-page summary of the project.
- (d) A detailed project budget and budget narrative.

The application must include both a detailed budget and a budget narrative for the proposed project.

At a minimum, the detailed budget should separately itemize for each year of the proposed project all direct project costs including, but not limited to, costs for personnel, consultants, equipment, travel and supplies. Applicants may use no more than 15% percent of grant funds for purchasing equipment, hardware or software. Applications which propose more than 15% for such purchases will be returned without review. With respect to personnel costs, the budget must specify for each position the salary or wages, fringe benefits and expected hours to be allocated to the project. The detailed budget must also disclose any indirect costs allocated to the project. For purposes of this grant, the allocated indirect costs may not exceed 20% of the direct costs.

The budget narrative must be limited to five pages. The budget narrative must propose a date on which the applicant wants funding to start, specify the duration of the project, explain the assumptions underlying each line item of the budget and provide a

justification for the proposed costs. This includes an explanation of how the indirect cost rate was developed and what costs are included therein.

Expenditures of the grant funds must adhere to the specific line items in the applicant's approved grant budget. Transfers between line items (increases and decreases) must be requested in writing and approved in advance by the FMMJUA's General Manager.

No applicant may include in the budget a fee or other charge that is in excess of the Applicant's actual direct and indirect project costs.

The RFA does not require cost sharing. However, in the scoring of the criterion relating to Agency or Institution Support and Commitment (Section 4.2), the FMMJUA will take into account the resources that each applicant and its partners intend to devote to the project being proposed. Institutional support from the applicant and its partners indicates a greater potential for project success and sustainability. Example of institutional support would include donated equipment and space, institutional funded staff time and effort, or other resource investments. In this regard, the budget should include line items that specify the resource contributions, if any, by the applicant and its partners. The budget narrative should describe these contributions and provide assurances that the applicant and any partners are committed to providing these funds and resources for the duration of the project.

The feasibility and appropriateness of the budget is a factor in funding decisions.

(e) Audited financial statements for the applicant, including, at a minimum, income statements and balance sheets covering the applicant's two most recent fiscal years.

If the applicant has no audited statements, then the applicant must submit its unaudited financial statements for the same time period.

In addition, the primary investigator and co-investigators should submit their Other Support page in National Institutes of Health format. See https://grants.nih.gov/grants/forms/othersupport.htm.

- (f) Body of proposal (up to 25 double-spaced pages on 8 ½ x 11 sized paper with one inch margins and a font size no smaller than 12 points), which shall include the following sections:¹
 - 1. Project Description: At a minimum, the project description should:
 - a. Identify the patient safety issue or problem targeted, including whether this problem arises in an inpatient or an outpatient setting (or both), the scope of the issue or problem, and the population most at risk. Describe the patient safety issue or problem in sufficient detail to render a complete

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¹ See section 3.2(g) below regarding the Appendix.

understanding of the nature of the problem that is to be addressed and how the safe practice intervention to be developed and implemented will eliminate and/or mitigate the identified risks and hazards. This description should include not only a brief review of the salient literature with respect to the problem area, but also the anticipated benefits, limitations, and scientific significance of the proposed safe practice to be designed and implemented.

b. Describe the development and implementation of the proposed intervention that addresses the identified risks and hazards. The Applicant must have already completed the risk assessment to such a degree that it can be used as part of the process to develop and implement the safe practice intervention. The applicant must include information as to how the risk assessment/modeling has been incorporated into the planning for the safe practice intervention intended to eliminate or minimize the patient safety risk or potentially hazardous health care practice that was assessed and/or modeled. The applicant must identify the patient population most impacted by the risks and hazards and outline the expected benefits and outcomes from the implementation of the safe practice.

This includes human subject protection and Institutional Review Board oversight. If the study involves patient recruitment then details of informed consent and all study instruments should be included so they may be evaluated. A data protection plan adhering to the Health Insurance Portability and Accountability Act is expected.

- c. Describe the specific health care organization, setting of care, or specialty practice area in which the proposed intervention will be implemented, including an explanation of why those chosen are particularly suitable for this intervention.
- d Given the specification of the research objectives and taking into account practical constraints, the applicant needs to describe the methodology to be employed, including the specific outcomes that will be measured and analyzed to demonstrate successful achievement of the project objectives. Information provided in the application should include the anticipated benefit to established knowledge about how to improve patient safety. The application must include a timeline with milestones covering all major phases of the project.
- e. Describe the applicant's plans for collecting outcome data, including types of data; analyzing the outcome measures and how they relate to the project objectives; provisions for ensuring the privacy and confidentiality of individually identifiable health information; and anticipated benefits of a successful intervention to patient safety and safer provision of health care

services. To the extent possible, applicants should discuss the generalizability and any anticipated limitations of the proposed intervention.

- f Describe how the applicant plans to engage and involve its partners and significant stakeholders in the project.
- Provide a project management plan, which should include an g. implementation plan including a timeline for introducing the safe practice intervention into the health care delivery process. This plan should include the identification of barriers and problems to be overcome in introducing the safe practice intervention. The plan should discuss the anticipated costs and benefits to the agencies or institutions of implementing the safe practice intervention, including the projected return on investment for the intervention development and implementation. If appropriate for the proposed intervention, the project management plan should include the human subjects' protection plan, including Institutional Review Board review. The applicant must demonstrate that it has adequate and appropriate insurance and/or self-insurance and that it will be able to meet the indemnification requirements of the RFA, and specifically, but not limited to, paragraph 15 of the Grant Agreement, attached hereto as Appendix D.
- h. Describe potential barriers to adoption of the safe practice intervention and how these barriers can be overcome.
- i Describe anticipated products, including any implementation toolkits that will result from the project. The applicant should specify projected impact and replicability of any tools, products and the toolkits that are developed. A toolkit should include implementation specifications and guidelines as well as data specifications when necessary; document the lessons learned during the implementation process, including the barriers and challenges and how they were addressed; and identify any resources (e.g., staff, costs) and other tools that facilitate adaptation and/or adoption of the safe practice intervention.
- j. Provide an evaluation plan. The plan should focus on the performance and impact of the implementation of the safe practice intervention. The applicant should describe how the safe practice intervention (including the implementation toolkit or other products) and project outcomes will be evaluated and assessed. The evaluation plan should also focus on assessing the reproducibility, generalizability, benefits, and costs of the safe practice intervention.

- k. Provide a dissemination plan. The dissemination plan should describe how the applicant intends to actively promote and share the intervention tools/toolkit with other interested parties outside of the applicant organization and its partner(s). This information should be in the form of an action plan for sharing the adaptation and/or adoption of the planned implementation toolkit by other health care organizations.
- 1 The applicant must describe how the project will be integrated into the mainstream or normal operations and activities of the organization for sustainability. There is an expectation that the safe practices successfully implemented as part of the funded activities will become standard operating procedures/practices with the organization.
- 2. Organization: This section of the proposal should describe the organization's commitment to patient safety in either an inpatient and/or an outpatient setting, including previous safety initiatives the organization has undertaken (whether funded as a project or implemented as part of regular operations). Organizational experience implementing projects similar in scope to the project proposed to the FMMJUA should be highlighted. If similar projects have not previously been implemented, the organization should explain why it expects to succeed in implementing this project. Partnerships with other organizations should be detailed, including the role each organization will play in the project and any previous collaborative efforts the organizations have had together.
- 3. Personnel: Biographical descriptions of key personnel, including the PI, must be provided along with a description of each individual's expected role in the project and previous experience with patient safety initiatives and projects the individual has participated that were funded with money received through a grant. If staff is not currently available for the project, the applicant should describe the recruiting efforts, including the skills and experience an individual will need in order to staff the project. The likelihood of recruiting an individual to meet these qualifications should also be described. Contingent hires should be identified.

In addition, a current National Institute of Health (NIH) personal biosketch is expected for the principal investigator and those serving as Co-Investigators.

The PI should be an experienced senior level individual who should devote a substantial portion of his/her time to the project.

4. <u>Complaints</u>: Applicants shall identify all written complaints or demand letters it has received in the last five years in conjunction with a project or grant that is similar to the project being proposed in this application. A copy of such complaint or letter should be attached. Applicants should include a brief explanation of the situation and its resolution. If none exist, affirmatively state so.

- 5. <u>References</u>: Applicants shall furnish a minimum of three references that can explain the applicant's ability to successfully complete the proposed project. These references should be professionals in an area related to the project and should have personal knowledge of the applicant's abilities. References should be provided in the form attached as Appendix C.
- 6. <u>Financial Conflicts of Interest</u>: The names of study personnel are required to report any real or perceived financial conflicts of interest. This includes patents, stocks, consulting, etc. of the study personnel or family members related to the proposed intervention. Please refer to ICMJE Form for Disclosure of Potential Conflicts of Interests: http://www.icmje.org/conflicts-of-interest/.
- (g) Appendix: The PI's resume or C.V., along with the resumes or C.V.'s for other key project personnel, must be included in the appendix. In addition, if an applicant proposes to work jointly with one or more organizations on the project, a memorandum of understanding or letter of intent demonstrating an agreement to work together on the grant project must be provided. Applicants may attach other supplemental materials that they feel may improve the quality of their proposal. Supplemental materials are limited to a total of 20 pages and must be contained in appendices to the main application. Resumes, C.V.s, MOUs, and letters of intent do not count towards the 20-page limit for supplemental materials.

TO **ENSURE EOUITY AMONG** APPLICANTS, **PAGE** NUMBER, MARGIN, FORMATTING, AND **FONT SIZE** REQUIREMENTS **MUST** \mathbf{BE} **OBSERVED.** APPLICATIONS VIOLATING THESE REQUIREMENTS WILL NOT BE REVIEWED.

SECTION 4: APPLICATION REVIEW INFORMATION

4.1 Responsiveness Review

Upon receipt, applications will be reviewed for responsiveness to the requirements in the RFA:

- (a) Applications found to be responsive to the mandatory requirements in the RFA will be evaluated pursuant to Section 4.2 below.
- (b) Applications found to deviate materially from the mandatory requirements will be rejected and not further evaluated. The use of "shall," "must," or "will" in this RFA indicates a mandatory requirement or condition from which a material deviation may not be waived by the FMMJUA. A deviation is material if, in the FMMJUA's sole discretion, the deficient response (i) is not in substantial accord with the RFA requirements, (ii) gives one applicant an advantage or benefit not enjoyed by other applicants, (iii) impairs the ability to do a complete evaluation of an application, and/or (iv) adversely impacts the FMMJUA's interests.
- (c) The FMMJUA may reject any application not submitted in the manner specified by the RFA. However, the FMMJUA reserves the right to waive any minor irregularity, technicality, or omission if the FMMJUA determines that doing so will serve the FMMJUA's best interests. Waivers, when granted, shall in no way modify the RFA requirements or excuse the applicant from full compliance with the RFA specifications if the applicant is awarded a grant.
- (d) The words "should" or "may" in this RFA indicate desirable attributes or conditions, but are permissive in nature. Deviation from, or omission of, such desirable features will not in itself cause rejection of an application.
- (e) Unless specifically requested by the FMMJUA, any amendments, revisions, or alterations to proposals will not be accepted after the application receipt deadline. If the FMMJUA determines that an application contains a nonmaterial error, the FMMJUA may notify the applicant and provide the applicant with an opportunity to correct the error. Information that is required to be included in an application and is inadvertently omitted will not be accepted under this error correction provision. All information required to be included in an application must be received by the application submission deadline specified in Section 1.9 of this RFA.

4.2 Application Evaluation and Selection

An application evaluation committee consisting of at least three members with experience and knowledge in the areas and requirements for this RFA will score each complete and responsive application. The FMMJUA reserves the right to have specific sections of the applications evaluated by less than three individuals. The applications will be evaluated based on the following criteria:

(a) Significance (20 possible points):

- Does the proposed project address an important patient safety problem and will it ultimately show a reduction in medical professional liability claims?
- Will the proposed safe practice intervention make a difference in patient care and improve patient safety?
- If the aims of the project are achieved, how do they improve the safety of health care services?
- If the aims of the project are achieved, how do they advance the diffusion and adoption of effective safe practices in Florida?
- What are the overall benefits to patients and society of implementing the safe practice intervention?

(b) Approach (20 possible points):

- Does the application adequately demonstrate the completion of a risk assessment and/or gap analysis for the problem and the safe practice intervention?
- Is the proposed intervention appropriate and reasonable given the risks and hazards identified?
- If the proposed intervention involves risks to human subjects, including risks to privacy and confidentiality, will the human subjects' protection plan be reviewed by an Institutional Review Board (IRB)? If so, has the applicant agreed to provide the final IRB approval letter?
- Is there a clearly demonstrated scientific basis for the proposed intervention that supports a likelihood of success?
- Is there a clear plan for implementation including a project management plan, measurable outcomes, timelines, and milestones?
- Does the project plan have clear and well-reasoned goals consistent with those stated in this RFA?
- Does the application acknowledge potential problem areas and consider alternative tactics?
- Are any barriers to adoption and difficulties in implementation adequately addressed?
- Does the application adequately demonstrate the ability of the applicant to meet the indemnification requirements of the RFA and the Grant Agreement and the sufficiency of the applicant's insurance and/or self-insurance coverage?

(c) <u>Investigators (10 possible points)</u>

- Are the PI and other key personnel appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to the experience level(s) of the PI and other members of the project team?

- Do the PI and project team bring complementary and integrated expertise to the project as appropriate?
- Has the project included outside resources or partners that have expertise in implementing safe practice interventions if such expertise does not exist within the agency or institution seeking the grant award?

(d) Agency or Institution Support and Commitment (10 possible points):

- Does the application provide evidence that the agency or institution has sufficient influence, experience, and resources to carry out the proposed activities?
- Is there a substantial level of agency or institution support for the proposed project?
- Is there thorough and convincing evidence and documentation of the commitment of the agency or institution?
- Is the type and extent of the agency or institution's resource commitment an appropriate commitment to patient safety?
- Is this project part of an ongoing effort to improve patient safety, or is there other evidence that the agency or institution has a history of successful efforts in improving patient safety?
- Is there evidence of agency or institutional support and commitment to sustaining and institutionalizing the safe practice intervention once the funding has been completed?
- Are the resources dedicated to the project sufficient to ensure commitment on the part of key personnel?
- To what extent does the project involve stakeholders at multiple levels of the organization?
- Is the agency or institution partnering with another agency or institution and, if so, are the details and benefits of such an arrangement described, and is there evidence of commitment from the collaborating partner(s)?

(e) Environment (10 possible points):

- Does the environment in which the project will be conducted contribute to the probability of success?
- Does the proposed project benefit from unique features of the health care environment(s) or subject populations?

(f) Generalizability (10 possible points):

- How generalizable would the safe practice intervention be to other settings of care and/or other health care organizations?
- Can the implementation products or toolkit for the safe practice intervention resulting from the project be adapted and/or adopted by other parts of the applicant agency or institution and other types of organizations?
- Are there adequate plans to address the needs of gender, racial and ethnic groups (and subgroups), and children as appropriate for the aims of the project?

• Has adequate attention been given to any specific issues in the provision of health care services and safety of Floridians and the needs of specific Florida populations?

(g) Budget (10 possible points)

- Is the proposed budget reasonable and is the requested period of support appropriate in relation to the proposed research project?
- Is the proposed budget allocation appropriate for the project objectives?
- Does the resource allocation allow for the effective development and implementation of the proposed intervention and the resulting tools, products and toolkit?
- Is there effective and efficient use of project resources?
- Does the budget reflect the costs associated with any arrangement with participating partners?

(h) Responsibility (10 points)

- Have there been any complaints or demand letters received by the applicant?
- If so, were the issues adequately resolved?
- Do the references indicate that the applicant and the applicant's project will likely be successful?
- Are the references knowledgeable about the project area and the applicant's ability?
- If applicant is a current or past grantee, did the applicant meet all deadlines and requirements of FMMJUA grant program?

After the evaluation team members independently score the applications, the evaluation team will meet in a public meeting to review the scores and to ensure that the evaluators did not misunderstand or overlook information contained in the applications. The meeting is not intended to achieve any group scoring, but evaluators may change their scores based on information discussed at themeeting. The General Manager will then rank the applicants based on the evaluation scores. Members of the public will not be permitted to speak at this meeting.

The General Manager will then provide the applications, tabulated scores, and rankings to an RFA Selection Committee ("Committee") appointed by the Board Chair. The Committee will ask some or all of the applicants to make an oral presentation. If an oral presentation is requested, the applicant MUST attend the oral presentation either in person or by video teleconference. While the FMMJUA anticipates applicant presentations, the FMMJUA reserves the right to award the grants without any presentations.

These presentations will take place in a public meeting. Members of the public will not be permitted to speak at these presentations. The Committee will meet in a later public meeting to consider the applications and develop a recommendation as to what action the Board should take.

4.3 Award

The Board will make the final decision on what grant(s), if any, to award pursuant to this RFA at one of its public meetings. Members of the public will be permitted to address the Board at this meeting, but an individual is limited to 5 minutes. An entity is only allowed to have one authorized representative address the Board on a particular issue.

The Board will award the grant(s) to the applicant(s) which offers the best value as measured by the criteria stated in this RFA. The FMMJUA reserves the right to approve one or more grant requests, or to reject all requests, at its discretion. The FMMJUA also reserves the right to reduce or delete any budget items or the total amount of the budget at its sole discretion.

The FMMJUA will notify applicants of the award decision by posting that decision on the FMMJUA website. Selection of an application for award is not authorization for performance to begin. Funding shall be subject to the execution of the Grant Agreement between each awardee and the FMMJUA, which memorializes the terms of the Grant including the start date, and receipt of the signed MOU, if applicable.

4.4 Clarifications

The FMMJUA reserves the right to seek clarification of any information contained in an application. The failure of an applicant to provide any requested information may result in rejection of the application.

APPENDIX A

SAFETY OF HEALTH CARE SERVICES GRANT APPLICATION COVER SHEET

AGENCY/INSTITUTION NAME: _	
ADDRESS:	
TELEPHONE NUMBER:	
FACSIMILE NUMBER:	
E-MAIL ADDRESS:	
PRINCIPAL INVESTIGATOR:	
TITLE AND BRIEF SUMMARY O	F GRANT PROJECT:
REQUESTED GRANT AMOUNT:	
SIGNED (by individual author	orized to legally bind the organization):
Signature on this form constitutes accepted thereto.	ceptance of all the terms stated in the RFA and any addenda
	(Signature)
Name (Print):	
Title:	
Date:	

APPENDIX B

Acceptance of Grant Agreement

Appendix D is the Grant Agreement that will be executed by the parties if a grant is awarded pursuant to this RFA.

By signing this Acceptance, the undersigned certifies that I have read the Grant Agreement (Appendix D) and agree to abide by its terms and conditions.

If the applicant objects to any of the provisions in the Grant Agreement, the applicant must make a list of the terms it objects to and provide alternative language. The FMMJUA may, in its sole discretion, amend the Grant Agreement if it is in the FMMJUA's best interests. By signing the Acceptance of Grant Agreement form, the applicant agrees to be bound by the language in the Grant Agreement, even if FMMJUA chooses not to amend the language based on the applicant's objection.

AGREED TO AS OF THE DATE BELOW.	
Authorized Signature of Grant Applicant:	
D : (1)	
Printed Name:	
Title:	
_	
Date:	

APPENDIX C

REFERENCES

This form must be completed by the person giving the reference for the applicant. For the purposes of this reference, the applicant includes the organization, the principal investigator working on the Project, and the key personnel working on the Project. Upon completion of this form, please return the <u>original</u> to the applicant. You may attach additional sheets if necessary.

This reference is for (applicant's name):	
Name of the person providing the reference:	
Title of the person providing the reference:	
Organization name of the person providing the reference:	
Telephone number of the person providing the reference:	
Please identify your relationship with the applicant (specific principal investigator and key personnel as identified in the	
How long have you have had this relationship with applican	t:
Describe your knowledge of the applicant's ability to comport worked with the applicant on a similar type of project):	lete the proposed project (e.g., you supervised
Describe the applicant's ability to successfully complete the	proposed project:

Have you experienced any performance problems with the applicant? If so, explain:					
Are there any additional comments you would like to make regarding the applicant:					

APPENDIX D

Grant Agreement

Medica ("Gran	al Ma	s Grant Agreement ("Agreement") is dated,, and is between the Florida alpractice Joint Underwriting Association ("FMMJUA") and
# 2024	Care -01 (suant to its Plan of Operation, the FMMJUA established the Alvin E. Smith Safety of e Services Grant Program (the "Grant Program") and issued Request for Applications (the "RFA") for the purposes of funding projects that would improve the safety of services for all Floridians.
	or it	Grantee submitted an application ("Application") in response to the RFA requesting (the "Project"), which is more fully described in the a, as amended and incorporated by reference herein.
	Purs	suant to the Application, FMMJUA has awarded the Grantee a grant in the amount offor the Project (the "Grant"). The parties therefore agree as follows:
	1.	Contents of the Agreement. The Agreement consists of the terms stated herein and the Grantee's Application, including the budget. In the event of a conflict between the documents, the terms stated herein control and take precedence over the Application.
	2.	<u>Purpose and Administration</u> . Only the Grantee can spend Grant funds. The Grantee shall use the Grant funds consistent with the purposes and terms specified in the Application and this Agreement. In the event that the Grantee uses the Grant funds contrary to the purposes or terms stated in the Application and this Agreement (or any approved amendment thereto), the FMMJUA will terminate the Agreement, and the Grantee shall provide an accounting and repay the funds as provided for in paragraph 12 below.
		The Grantee will directly administer the Project being supported by the Grant. The Grantee agrees that no Grant funds shall be disbursed to any organization or entity, whether or not formed by the Grantee, other than as specifically set forth in the Application and Project budget, unless approved in advance in writing by the General Manager of the FMMJUA.

3. Grant Period. The Grant Period shall begin on_____and end on____.

4.	Grant Amount and Disburs	ement of Funds. The total Grant amou	unt of
	is to be paid in four installr	ments, with one installment paid every	six months.
	The initial installment of	, which is for the first budge	t six months, will be
	paid on or before	The second installment of	, which is for
	the second budget six mor	nths, will be paid on or before	The third
	installment of	, which is for the third budget six mor	nths, will be paid on
	or before	. The final installment amount of	, which is
	for the fourth budget six	months, will be paid on or before	The
	remaining payments are su	bject to the FMMJUA's review and ac	eceptance of the six-
	month progress report, as d	escribed in paragraph 7, below.	

- 5. Memorandum of Understanding. If Grantee is not a health care provider organization, it must have a provider organization that is actively engaged in the delivery of health care as a participating partner in the proposed project. Grantee must submit a understanding ("MOU") memorandum of signed by the provider organization/participating partner specifying the partner's commitment to the proposed project. A copy of the MOU must be submitted to the FMMJUA General Manager before the first installment of the grant is distributed. Notwithstanding the dates listed in section 4 above, no money will be distributed until the MOU is provided to the FMMJUA.
- 6. <u>Budget</u>. The Grantee shall adhere to the specific line items of the detailed Project budget submitted in its Application when expending Grant funds. In order to transfer funds between line items (increases and decreases), the Grantee must make a request in writing to the FMMJUA General Manager and receive written approval from the General Manager in advance of the transfer. No applicant may include in the budget a fee or other charge that is in excess of the applicant's actual direct and indirect project costs.
- 7. Accounting and Audit. The Grantee shall keep a systematic record on a fund-accounting basis of the receipt, disbursement, and expenditure of Grant funds. The Grantee shall retain the substantiating documents, such as bills, invoices, canceled checks, receipts, etc., in the Grantee's files for a period of not less than five (5) years from the date of the expiration of the Grant period. The Grantee shall promptly furnish the FMMJUA with copies of such documents upon the FMMJUA's request and without charge to the FMMJUA. The FMMJUA, at its expense, may audit or have audited the records of the Grant Applicant insofar as they relate to the disposition of funds granted by the FMMJUA. If an audit occurs, the Grantee shall provide all necessary assistance in connection with the audit without charge to the FMMJUA.

8.	Reports. The Grantee shall submit a progress report every six months. The report is
	due on the 15th of the month prior to the next scheduled installment disbursement
	(e.g., the first report will be due on, and the second installment will be
	disbursed on). This progress report must include descriptive and
	evaluative comments on both completed activities and plans for the remainder of the
	Project, including any changes foreseen in the future. At a minimum, the progress
	report will include descriptive comments on the following: progress to date measured
	against project aims; methodological changes implemented; key preliminary findings;
	significant problems and resolutions; inclusion of priority populations; a list of
	expenditures charged against this Agreement, including a description of the purchase,
	the date of the purchase, the vendor's name, and the amount paid; and projected related
	publications, presentations, and dissemination activities. Funding for each of the last
	three installments is contingent upon review and acceptance by the FMMJUA of each
	progress report.

The Grantee shall submit a detailed final progress report to the FMMJUA on or before .

The Grantee shall submit a financial report for each fiscal year contained within the Grant Period accompanied by a report of the auditors prepared according to standards presented in AU Section 551, "Reporting on Information Accompanying Basic Financial Statements in Auditor-Submitted Documents" (July 16, 2008), no later than 180 days after the close of the fiscal year. The financial report is to be in the same format as the approved Grant budget, and for each line item, show the original Project budget, the balance carried forward as of the report date, the amount expended against each line item for the current period, and the resulting balance remaining in each line. A total is to be shown for each column. The financial report may be included with the basic financial statements and other supplementary information or it can be presented separately in an auditor-submitted document outside the basic financial statements. If an encumbrance system is used, encumbrances are to be shown in a separate column from cash expenditures.

- 9. <u>Monitoring</u>. The FMMJUA may, at its expense, monitor and conduct an evaluation of operations under the Grant, which may include visits by representatives of the FMMJUA or its designees to observe the Grantee's Project procedures and operations and to discuss the Project with the Grantee's personnel.
- 10. <u>Public Reporting</u>. The FMMJUA may ask the Grantee to review and approve a project summary briefly describing the Grantee's activity, which will be used by the

FMMJUA to respond to inquiries and for other public information purposes.

The Grantee shall send to the FMMJUA copies of all papers, manuscripts, and other information materials that it produces that are related to the Project.

In all public statements concerning the FMMJUA (including publications, press releases, annual reports, or other announcements) the Grantee shall refer to the FMMJUA by its full legal name: Florida Medical Malpractice Joint Underwriting Association.

- 11. Certification Required When Grant Is Used for Research Involving Human Subjects. If the Grant is to be used in whole or in part for research involving human subjects, the Grantee hereby certifies that it will comply with all applicable state and federal laws and regulations regarding such research, including any applicable privacy regulations. If the proposed intervention involves human subjects research, the Grantee will certify that they will have the research reviewed by an Institutional Review Board (IRB). The IRB must approve the research before research activities involving human subjects may begin.
- 12. <u>Termination and Cost Recovery</u>. The FMMJUA may terminate this Agreement for cause upon such written notice that is reasonable under the circumstances. Cause shall include, but not be limited to the following: misuse of funds; fraud; lack of compliance with applicable laws, rules, or regulations; failure to perform in a timely manner; failure to submit required reports; and a material breach of any provision of this Agreement.

The FMMJUA may, for its sole convenience, cancel this Agreement in whole orpart, at any time, by giving the Grantee 30 calendar days' written notice of its intention to do so.

The FMMJUA may terminate this Agreement if the FMMJUA determines, in its sole discretion, that continuation of the Agreement would not produce beneficial results commensurate with the further expenditure of funds, by providing the Grantee with 30 calendar days' written notice.

In the event of termination by the FMMJUA, the Grantee will be entitled to recover all approved project costs incurred prior to the date of termination.

The Grantee may terminate this Agreement if the Grantee determines that it cannot adequately complete the Project by providing the FMMJUA 30 days' written notice

of its intention to do so. If the Grantee terminates this Agreement, Grantee will provide to the FMMJUA the products and materials developed in whole or in part, with the FMMJUA funds in accordance with paragraphs 14 and 20, below.

If this Agreement is terminated prior to the scheduled completion date, the Grantee shall, upon request of the FMMJUA, provide to the FMMJUA a full accounting of the receipt and disbursement of the funds and expenditures incurred under the grant as of the effective date of termination. The Grantee shall also repay within 30 days after written request by the FMMJUA all Grant funds unexpended as of the effective date of termination and all Grant funds expended for purposes or items allocable to the period of time subsequent to the effective date of termination. The Grantee shall also repay within 30 days after written request by the FMMJUA all Grant funds expended for purposes or items not authorized by the FMMJUA as detailed on the Project budget.

- 13. Remedies. In lieu of termination, in the event of any breach of this Agreement or failure to perform under this Agreement, the FMMJUA, at its sole discretion, may provide reasonable notice of the breach and an opportunity for the Grantee to cure the breach or performance within a reasonable time period. The FMMJUA may withhold or suspend payments until the deficiency is cured. The FMMJUA has the sole discretion to determine whether the Grantee has cured the deficiency. Providing the Grantee with the option to cure the deficiency does not waive FMMJUA's right to terminate the Agreement or pursue any other appropriate remedies available by law.
- 14. <u>Grant Reservation</u>. Any portion of the Grant unexpended at the completion of the Project or the end of the Grant Period, whichever occurs first, shall be returned to the FMMJUA within 30 days thereof.
- 15. <u>Limitations and Changes</u>. Any changes, additions, or deletions to the conditions of the grant must be made in writing only and must be jointly approved in writing by the FMMJUA and the Grantee.
- 16. <u>Indemnification</u>. To the extent not prohibited by Florida law, the Grantee shall be liable for, and shall indemnify, defend, and hold the FMMJUA and its officers, employees, agents, committee, and Board members harmless from all claims, suits, judgments, or damages (including litigation costs and reasonable attorney's fees) arising from the award of the Grant or the performance of the Project or any project funded in whole or in part by such Grant.
- 17. Controlling Law. This Agreement and all documents incorporated herein shall be

construed and enforced in accordance with the laws of the State of Florida.

- 18. Arbitration. Any controversy, claim or dispute arising out of or relating to this Agreement shall be settled by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association, in Tallahassee, Florida, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. There will be three arbitrators, named in accordance with such rules.
- 19. <u>Conflict of Interest</u>. Grantee shall notify the FMMJUA of any officer, director, owner, employee or agent of the Grantee who is also an FMMJUA employee, agent, officer, Board, or committee member. Grantee shall notify the FMMJUA of any FMMJUA employee, agency, officer, Board, or committee member who owns, directly or indirectly, an interest of five percent or more in the Grantee or its affiliates. In the event that it is determined that the Grantee did not disclose information in this section in its application, the FMMJUA will terminate this Agreement.
- 20. <u>Public Access to Records</u>. Unless exempt by law, all documents, papers, letters, or other materials that are made or received by the Grantee in connection with the Agreement may be subject to the Public Records Law pursuant to Chapter 119, Florida Statutes.

All documents, papers, letters, electronic transmissions, or other materials that are made or received by the Grantee in connection with the grant or contract shall be maintained for a period of five years after the expiration of the grant period. The FMMJUA may cancel this Agreement in the event of the Grantee's refusal to allow access to public records in accordance with Chapter 119, Florida Statutes.

If the Grantee considers any portion of documents, data, or records provided to the FMMJUA to be trade secret and exempt from public record disclosure, the Grantee must clearly mark the information as "Trade Secret Material" and submit a separate redacted electronic copy of the material. The first page of the redacted copy and each page on which information is redacted shall display the phrase "Redacted Copy." Failure to mark an application as trade secret waives the exemption.

The FMMJUA is not obligated to agree with the Grantee's claim of exemption and the Grantee is responsible for defending its claim that each of the redactions is exempt from inspection and copying under Florida's Public Records Law.

21. <u>Intellectual Property</u>. The Grantee may copyright or seek patents for, as appropriate,

final and interim products and materials developed in whole or in part with FMMJUA grant funds, including, but not limited to, methodological tools, measures, software with documentation, literature searches, and analyses. Such copyrights and patents are subject to a worldwide irrevocable FMMJUA license to use and permit others to use these products and materials for the FMMJUA purposes, which may include making project materials, databases, results, and algorithms available for verification or replication by other researchers. In addition, final products may be made available to the health care community and the public by the FMMJUA or its agents if such distribution would significantly increase access to a product and thereby produce substantial or valuable public health benefits.

- 22. The Grantee and its personnel shall comply with all applicable federal, state, and local laws, rules, and regulations in performing under this Agreement.
- 23. It shall be the sole responsibility of the Grantee to immediately notify the FMMJUA, within 24 hours, of the occurrence of any of the following: a change of the Principal Investigator; a change of any personnel assigned to this Grant project; a change in the legal status of the Grantee; a change in the licensure status of the Grantee, or of any of the personnel assigned to this Grant project; criminal charges alleged against or criminal convictions of the PI or any personnel assigned to this Grant project; complaints received by the Grantee; regulatory or administrative complaints or charges.
- 24. The FMMJUA's project manager for this Agreement is identified below.

[INSERT Project Manager's name and contact information.]

25. The Grantee's project manager for this Agreement is identified below.

[INSERT Project Manager's name and contact information.]

The parties	are signing	this Agre	ement as	of the	date stated	in the	introducto	ory cla	iuse.
FLORIDA	MEDICAL.	MALPR	ACTICE	IOINT	UNDERV	VRITI	JG ASSO	CIAT	ION

By:	_
Name: Title:	
[INSERT NAME]	
By:	
Name: Title:	