

**Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
*Narrowing the Time Gap between Onset of Symptoms and Treatment for RA***

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to partner with the global healthcare community to improve patient outcomes in areas of mutual interest through support of measurable learning and change strategies. “Independent” means that the projects funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

The intent of this document is to encourage organizations with a focus in healthcare professional education and/or quality improvement to submit a letter of intent (LOI) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need. The RFP model is a two-stage process. Stage 1 is the submission of the LOI. After review of the LOI, you may be invited to submit your Full Grant Proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer IGLC website (www.pfizer.com/independentgrants) in the Request for Proposals section and is sent via e-mail to all registered users in our grants system. Some RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.

II. Eligibility

Geographic Scope:	<input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International(specify country/countries)_____
Applicant Eligibility Criteria:	<p>The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; and other entities with a mission related to healthcare improvement.</p> <p>More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf.</p> <p>Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project. For programs offering credit, the requesting organization must be the accredited provider.</p>

III. Requirements

Date RFP Issued:	November 16, 2015
Clinical Area:	Rheumatoid Arthritis (RA)
Specific Area of Interest for this RFP:	<p>It is our intent to support projects that focus on closing the gap in time between the onset of symptoms indicating RA and initiation of appropriate DMARD therapy. Measures of success should include time to treatment as a metric. The use of disease activity measures as an outcome measure is encouraged. Projects that employ well-considered, systems-based changes likely to result in patient outcomes improvement will be given priority during review.</p> <p>The ability of a project to be replicated at other institutions will be a key consideration when reviewing projects. Projects that can be disseminated and impact a wide range of demographic groups will be a priority. Institution-specific information that would inform health-systems in other practices and settings should be provided. Another key consideration is the ability of a project to be feasibly implemented in a busy clinic setting without significantly increasing the clinic burden. Partnerships between academic/research and community based institutions are highly encouraged.</p> <p>A thorough evaluation designed to follow generally accepted educational and scientific principles is expected. During the grant review, the intended outcome of the project is given careful consideration, and if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given high priority. When developing an educational element applicants can find more information on principals of learning and behavior change for health professionals here.</p> <p><i>It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.</i> Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/iir.</p>
Target Audience:	Rheumatology healthcare professionals and colleagues involved in managing adult patients on both a patient and system level.

<p>Disease Burden Overview:</p>	<p>RA, the most prevalent type of inflammatory arthritis, affects more than 1.5 million adults in the U.S.¹ Though the progression of RA can vary greatly from patient to patient^{2,3}, joint damage occurs most rapidly during the first several years.²⁻⁶ There is strong evidence suggesting clinical outcomes are improved by use of therapy, including reduction in joint signs and symptoms, improvement in physical function, inhibition of progression of joint damage, and reduction in long-term disability.⁷ Additional evidence on therapeutic strategies has evolved over the last two decades that supports diagnosis and treatment very early in the course of disease, and treatment to a defined target such as clinical remission or low disease activity.⁷⁻⁹</p>
<p>Recommendations and Target Metrics:</p>	<p>Related Recommendations</p> <ul style="list-style-type: none"> • 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis.¹⁰ • 2012 ACR recommendations for use of RA disease activity measures in clinical practice.¹¹ • ACR Referral Guidelines.¹²
<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>There is evidence to suggest the early diagnosis of RA (within 3 months of disease onset) along with the rapid inception of therapy can significantly improve patient outcomes and minimize long-term disabilities.^{5,6,13-17} Some go so far as to suggest RA may be more amenable to treatment ‘early’ (within 3 months from symptom onset) in its presentation and that treatment at this time can impact the long-term trajectory in a way that later treatment cannot achieve.¹⁸⁻¹⁹</p> <p>The initial diagnosis of RA typically occurs in the primary care setting with referral to a rheumatologist for confirmation and management.^{20,21} Wait times from referral by the primary care provider to rheumatology consultation can be longer than 3 months.^{22,23} This wait is compounded by the fact that many patients can take more than 3 months from symptom onset to seek initial care in a primary care setting.²⁴</p> <p>There are limits to patient access to rheumatology care in rural and underserved U.S. communities due to an aging workforce, uncertain business climate and government regulation.^{25,26} In these situations, primary care providers must decide between initiating treatment in this setting or referring patients to a rheumatologist and possibly delaying treatment.²⁷</p>

<p>Barriers:</p>	<p>There are 3 main reasons cited for delays in care: patient delays in seeking care from their primary care provider; delays by the primary care provider in referring the patient to a rheumatologist; and delays by the rheumatologist in assessing the patient after referral.^{28,29,30}</p> <p>Patients may delay in seeking help because they are not aware of RA, their risk of RA, that their symptoms represent RA, or that these symptoms are indicative of a disease where prompt intervention can improve long-term outcome.³¹</p> <p>It has been noted that patient access to rheumatologic care is one of the primary obstacles to early diagnosis. Many patients presenting in the first states of RA are seen by a primary care physician. While rheumatologic consultation would be highly advantageous at this time, it may be difficult for patients due to referral wait-times taking weeks to months for many rheumatologists.^{22,23}</p>
<p>Current National Efforts to Reduce Gaps:</p>	<p>The American College of Rheumatology has recently developed a website designed to assist rheumatologists with practice improvement, local population management, and efficient, successful participation in national quality programs.³²</p> <ul style="list-style-type: none"> • Rheumatology Clinical Registry http://www.rheumatology.org/Practice/Clinical/Rcr/Rheumatology_Clinical_Registry/
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>Individual projects requesting up to \$330,000 will be considered. The total available budget related to this RFP is \$1,000,000.</p> <p>The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.</p>

<p>Key Dates:</p>	<p>RFP release date: November 16, 2015</p> <p>LOI due date: February 11, 2016 Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Review of LOIs by External Review Panel: Feb 25- March 16, 2016</p> <p>Anticipated LOI Notification Date: March 16, 2016</p> <p>Full Proposal Deadline: * April 11, 2016 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Review of Full Proposals by External Review Panel: May 2016</p> <p>Anticipated Full Proposal Notification Date: May 31, 2016</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: July 2016 to Jan 2019</p>
<p>How to Submit:</p>	<p>Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System". Registered users should select the LOI link under Track 1 – Learning & Change.</p> <p>If this is your first time visiting this site you will be prompted to take the Eligibility Quiz to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user.</p> <p>Select the following Area of Interest: Early Treatment in RA</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).</p> <p>If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page.</p>
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Susan Connelly (susan.connelly@pfizer.com), with the subject line "Early Treatment in RA 11-17-15]."</p>
<p>Mechanism by which Applicants will be Notified:</p>	<p>All applicants will be notified via email by the dates noted above.</p> <p>Applicants may be asked for additional clarification or to make a summary presentation during the review period.</p>

References:

1. Sacks JJ, Luo Y, and Helmick CG. Prevalence of Specific Types of Arthritis and Other Rheumatic Conditions in the Ambulatory Health Care System in the United States, 2001–2005. *Arthritis Care & Res* 2010;62:460–464.
2. Lee DM, Weinblatt ME. Rheumatoid arthritis. *Lancet* 2001;358(9285):903-911.
3. Gordon DA, Hastings DE. Clinical features of rheumatoid arthritis. In: Hochberg MC, Silman AJ, SJF, Weinblatt ME, Weisman MH, editors. *Rheumatology*. 3rd edition ed. New York, NY: Mosby; 2003. 765-780.
4. Lindqvist E, Jonsson K, Saxne T, Eberhardt K. Course of radiographic damage over 10 years in a cohort with early rheumatoid arthritis. *Ann Rheum Dis* 2003;62(7):611-616.
5. Kyburz D, Gabay C, Michel BA, Finckh A. The long-term impact of early treatment of rheumatoid arthritis on radiographic progression: a population-based cohort study. *Rheumatology (Oxford)* 2011;50(6):1106-1110.
6. Kyburz D, Finckh A. The importance of early treatment for the prognosis of rheumatoid arthritis. *Swiss Med Wkly* 2013;143:w13865.
7. O’Dell JR. Therapeutic Strategies for Rheumatoid Arthritis. *NEJM* 2004;350:2591-2602.
8. Nell VPK, Machold KP, Ebert G, Stamm TA, Uffmam M, Smolen JS. Benefit of very early referral and very early therapy with disease-modifying anti-rheumatic drugs in patients with early rheumatoid arthritis. *Rheumatology* 2004;43:906–914.
9. Lard LR, Visser H, Speyer I, et al. Early versus Delayed Treatment in Patients with Recent-onset Rheumatoid Arthritis: Comparison of Two Cohorts Who Received Different Treatment Strategies. *Am J Med*. 2001;111:446–451.
10. Singh JA, Saag KG, Bridges L, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Res* 2015;1–25. Available at: <http://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf>. Accessed Nov 11, 2015.
11. Anderson J, Caplan L, Yazdany J, et al. Rheumatoid arthritis disease activity measures: American College of Rheumatology recommendations for use in clinical practice. *Arthritis Care Res (Hoboken)*. 2012 May;64(5):640-7.
12. American College of Rheumatology. Referral Guidelines. Available at: <http://www.rheumatology.org/Portals/0/Files/Referral%20Guidelines.pdf>. Accessed Oct 27, 2015.
13. Emery P, Breedveld FC, Dougados M, Kalden JR, Schiff MH, Smolen JS. Early referral recommendation for newly diagnosed rheumatoid arthritis: evidence based development of a clinical guide. *Ann Rheum Dis* 2002;61:290–297.
14. Emery P. Evidence supporting the benefit of early intervention in rheumatoid arthritis. *J Rheumatol Suppl* 2002;66:3-8.
15. American College of Rheumatology. Guidelines for the management of rheumatoid arthritis: 2002 Update. *Arthritis Rheum* 2002;46(2):328-346.
16. Weinblatt ME, Kuritzky L. RAPID: Rheumatoid arthritis. *J Fam Pract* 2007;56(4):S1-S8.
17. Lukas C, Combe B, Ravaud P, Sibilia J, Landew R, van der HD. Favorable effect of very early disease-modifying antirheumatic drug treatment on radiographic progression in early inflammatory arthritis: Data from the Étude et Suivi des polyarthrites indifférenciées récentes (study and follow-up of early undifferentiated polyarthritis). *Arthritis Rheum* 2011;63(7):1804-1811.
18. Raza K, Buckley C, Salmon M, Buckley CD. Treating very early rheumatoid arthritis. *Best Practice & Research Clinical Rheumatology*. 2006; 20(5):849-863.

19. Raza K, Filer A. The therapeutic window of opportunity in rheumatoid arthritis: does it ever close? *Ann Rheum Dis* 2015 (Published Online First 10 March 2015). Available at <http://m.ard.bmj.com.proxy1.athensams.net/content/early/2015/03/10/annrheumdis-2014-206993.full>. Accessed Sept 24, 2015.
20. Hwang A, Gupta S, Liang MH. Identification of people with very early RA for optimal care: a public health challenge. *Nat Clin Pract Rheumatol* 2008;4(3):114-115.
21. Curtis JR, Arora T, Narongroeknawin P et al. The delivery of evidence-based preventive care for older Americans with arthritis. *Arthritis Res Ther* 2010;12(4):R144.
22. Cush JJ. Early rheumatoid arthritis -- is there a window of opportunity? *J Rheumatol* 2007;80:1-7. Available at <http://www.jrheum.org/content/80/1>. Accessed Sept 24, 2015.
23. Delaurier A1, Bernatsky S, Baron M, Légaré J, Feldman DE. Wait times for rheumatology consultation: is rheumatoid arthritis prioritized? *J Clin Rheumatol*. 2012 Oct;18(7):341-4.
24. Nanji JA, Choi M, Ferrari R, Lyddell C, Russell AS. Time to Consultation and Disease-modifying Antirheumatic Drug Treatment of Patients with Rheumatoid Arthritis — Northern Alberta Perspective. *J Rheumatol* 2012;39:707–11.
25. American College of Rheumatology, 2005 Workforce and Demographic Study
26. Quinn R. Long Delays For Appointments Underscore Need For More Rheumatologists. *The Rheumatologists*. August 2014. Available at: http://www.the-rheumatologist.org/details/article/6480751/Long_Delays_for_Appointments_Underscore_Need_for_More_Rheumatologists.html. Accessed April 1, 2015.
27. Margo K. The primary care perspective. *Am J Manag Care*. 2010;16:S259-S260.
28. Kumar K, Daley E, Carruthers DM, et al. Delay in presentation to primary care physicians is the main reason why patients with rheumatoid arthritis are seen late by rheumatologists. *Rheumatology (Oxford)* 2007;46:1438–40.
29. Villeneuve E, Nam JL, Bell MJ, et al. A systematic literature review of strategies promoting early referral and reducing delays in the diagnosis and management of inflammatory arthritis. *Ann Rheum Dis* 2013;72:13–22.
30. De Cock D, Meyfroidt S, Joly J, et al. A detailed analysis of treatment delay from the onset of symptoms in early rheumatoid arthritis patients. *Scand J Rheumatol* 2014;43:1–8.
31. Sacks JJ, Luo Y, and Helmick CG. Prevalence of Specific Types of Arthritis and Other Rheumatic Conditions in the Ambulatory Health Care System in the United States, 2001–2005. *Arthritis Care & Res* 2010;62:460–464.
32. American College of Rheumatology. Rheumatology Clinical Registry Available at: http://www.rheumatology.org/Practice/Clinical/Rcr/Rheumatology_Clinical_Registry/. Accessed September 24, 2015.

IV. Terms and Conditions

1. This RFP does not commit Pfizer or its partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.
2. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer to do so.
3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer IGLC. Applicants should not contact other departments within Pfizer regarding this RFP. Failure to comply will disqualify applicants.
4. Consistent with its commitment to openness and transparency, Pfizer reports education grants provided to medical, scientific, and patient organizations in the United States. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media. In the case of this RFP, a list of all LOIs selected to move forward may be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the IGLC website and/or any other Pfizer document or site.
5. Pfizer reserves the right to share with organizations that may be interested in contacting you for further information (e.g., possible collaborations) the title of your proposed project and the name, address, telephone number, and e-mail address of the applicant from the requesting organization.
6. To comply with 42 U.S.C. § 1320a-7h and 42 C.F.R. §§ 403.900-.914 (the Sunshine Act), Provider (sponsor) must provide to Pfizer specific information for the U.S.-licensed physicians and U.S. teaching hospitals ("Covered Recipients," as defined by applicable law) to whom the Provider (sponsor) furnished payments or other transfers of value from the original independent grant awarded by Pfizer. Those payments or transfers-of-value include compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and "items of value" (items that possess a discernible value on the open market, such as textbooks) provided to faculty and participants, if those faculty and/or participants meet the definition of Covered Recipient. Provider (sponsor) must submit the required information during the reconciliation process or earlier, upon Pfizer's request, so Pfizer can meet Sunshine Act reporting commitments. Be advised Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).

Frequently Asked Questions related to IGLC's Sunshine Act Reporting Requirements are available on our website (http://www.pfizer.com/files/IGLC_SunshineFAQ_Oct2014.pdf).

7. No portion of a Pfizer independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during the reconciliation process and/or the periodic collection of Sunshine reporting that funds were not used for food and/or beverages for learners and/or participants.

8. In the performance of all activities related to an independent grant, the Provider (sponsor) and all participants must comply with all applicable Global Trade Control Laws. "Global Trade Control Laws" include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP - Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.

9. For all Dissemination and Implementation research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal, which includes:
 - Obtaining institutional review board (IRB)/independent ethics committee (IEC) approval for studies involving human subjects or human tissue and obtaining a subsequent renewal of this approval as required by local regulations (e.g., yearly, biannually, etc.). In addition, obtaining any IRB/IEC approval for amendments to protocol as they pertain to the research.
 - Obtaining all required personal data privacy or informed consent documentation (as appropriate).
 - Obtaining all required regulatory approval(s) per local regulations.
 - Assuming all reporting obligations to local regulatory authorities.
 - A statement that the research will be conducted in compliance with relevant provisions of the International Conference on Harmonisation, Good Clinical Practice, or Good Pharmacoepidemiology Practice guidelines and all applicable local legal and regulatory Requirements

Appendix A: Letter of Intent Submission Guidance

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 3-page limit in the main section of the LOI. ***LOIs not meeting these standards will not be reviewed. It is helpful to include a header on each page listing the requesting organization.***

LOIs should include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Project Classification

1. There are multiple project types that are eligible for funding through this RFP. Please indicate which of the following best represents your project. More information on these classifications can be found in the Decision Matrix (Appendix B).
 - Dissemination and Implementation (D&I) Research
 - Quality Improvement
 - Education or Educational research
2. Background Information
 - It is expected that D&I research projects follow generally accepted principals. For all research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal. These are listed in the **RFP Terms and Conditions (#9)**.
 - At the time of approval of a full proposal, applicants will be required to sign a research contract, submit IRB approval and a research protocol.
 - Quality improvement projects should be described in terms of generally accepted principles of improvement science such as those described by the IHI model for improvement or LEAN.
 - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.
 - Educational projects should be planned using generally accepted principals of adult learning. More information on principals of learning and behavior change for health professionals can be found at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.
 - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.

C. Goal and Objectives

1. Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).
2. List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

D. Assessment of Need for the Project

1. Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in *your* target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.
- E. Target Audience
1. Describe the primary audience(s) targeted for this project. Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population
- F. Project Design and Methods
1. Describe the planned project and the way it addresses the established need.
 2. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.
- G. Innovation
1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
 2. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.
- H. Evaluation and Outcomes
1. In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data.
 2. Quantify the amount of change expected from this project in terms of your target audience.
 3. Describe how the project outcomes will be broadly disseminated.
- I. Anticipated Project Timeline
- J. Requested Budget
1. A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.
 2. The budget amount requested must be in U.S. dollars (USD).
 3. While estimating your budget please keep the following items in mind:
 - Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.

- The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
- It should be noted that grants awarded through IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).
- Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

K. Additional Information

1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize it in within the page limitations.

Organizational Detail (not to exceed 1 page)

Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.

Please note that any project partners listed in this section should also be listed within the online system. Tax-IDs of partner organizations will be requested when entering this information. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and a 1-page limit for organizational detail. If extensive, references may be included on 1 additional page. **Final submissions should not exceed 5 pages in total** (3 pages for the main section, 1 page for organizational detail, and 1 page for references).

All required sections should be combined in one document (MS Word or Adobe PDF). There is no need to submit the organization detail or references in a document separate from the main section of the LOI.

*Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit **WILL BE REJECTED and RETURNED UNREVIEWED.***

Appendix B: Project Classification Decision Matrix

Defining Question	Education/ Education Research	Quality Improvement	Dissemination & Implementation Research	Clinical Research
<p>Definition</p>	<p>Educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a healthcare professional uses to provide services for patients, the public, or the profession.</p> <p>A needs assessment is a systematic exploration of the need for education or training. The process involves first establishing who the learners are (i.e. what is their level of training and expertise) and then determining what skills they have, what skills they need and how best to deliver training to correct any deficiencies.</p>	<p>A process by which individuals work together to improve systems and processes with the intention to improve outcomes.</p>	<p>Identify, develop, evaluate and refine effective and efficient methods, systems, infrastructures, and strategies; to disseminate and implement research-tested health behavior change interventions, evidence-based prevention, early detection, diagnostic, management, quality of life improvement services, and data monitoring and surveillance reporting tools; into public health and clinical practice settings that focus on patient outcomes.</p>	<p>A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable clinical knowledge.</p>
<p>Who</p>	<p>HCPs</p>	<p>HCPs, Systems, Patients</p>	<p>HCPs, Systems, Patients</p>	<p>Patients</p>

Purpose	Identify knowledge gaps; close knowledge gaps	Understand and improve a process or patient experience; evaluate changes; close practice gaps; Solve a problem	Generate a knowledge base about how health information, interventions, and new clinical practices and policies are transmitted and translated for public health and health care service use in specific setting; Answer a question (hypothesis)	Generate knowledge; generalize knowledge; Answer a question (hypothesis)
Scope of Interest	HCP population (could be specialty-specific; institutional-specific; general)	Department, unit or patient population within an organization	HCP population or Institution-specific	General population (could be patients with specific condition)
Informed Consent Required	No	If appropriate	If appropriate	Yes
IRB Approval Required	No	Institutional-specific	Institutional-specific (review must occur resulting in documentation)	Yes
Outcomes Measured	Pre-, post-; self-attestation	Limited, simple, easy to use and administer; PDSA cycle	Randomized; Complex; Could include intervention reach; effectiveness; contextual factors influencing outcomes, and intervention costs.	Randomized; Complex; Patient-level
Data Collection	Minimal time, resources and cost	Minimal time, resources and cost	Complex, tightly controlled	Complex, tightly controlled
Regulated by	Organization	Organization	Organization, IRB, FDA, state and local laws	Organization, IRB, FDA, state and local laws

Grant Type	Education	Education (Medical)	D&I Research	Investigator Initiated Research (add link to website)
Example	<p>Knowledge (HCPs don't know something) <i>Example: Misdiagnosis because of lack of knowledge or understanding (knowledge gap)</i></p> <p>Competence (HCPs don't know how to do something, don't have methods or strategies) <i>Example: Suboptimal patient care because of lack of strategies or methods to intervene under certain clinical conditions (competence gap)</i></p>	<p>Implementation of a proven concept: Example: A health system implements a standing order procedure for recommended vaccines and rolls out measures related to workflow and training to put this into practice.</p> <p>The purpose of evaluation in this setting is to measure the impact of the intervention.</p>	<p>Study of non-therapeutic interventions: Example: An organization wants to know if a decision tool* can be used to improve patient care. The intent of this study is to compare the use of this tool vs standard care.</p> <p>The purpose of evaluation in this setting is to prove or disprove a hypothesis.</p> <p>*This could include a smart phone app</p>	<p>Study of therapeutic agents: Example: a study evaluating the comparative efficacy of two therapeutic agents**.</p> <p>The purpose of evaluation in this setting is to prove or disprove a hypothesis.</p> <p>**Drugs and devices</p>