Call for Letters of Interest from Potential Guideline Development Partners

DEVELOPMENT OF UPDATED AMERICAN COLLEGE OF RHEUMATOLOGY LUPUS NEPHRITIS GUIDELINE

Release Date: October 2, 2018

Deadline for Letters of Interest (receipt deadline): November 30, 2018

The American College of Rheumatology (ACR) requests letters of interest from teams or individuals who wish to partner with the ACR in developing an evidence-based clinical practice guideline for the management of lupus nephritis (LN). The final scope and clinical questions to be addressed in the guideline will be finalized after the guideline development team has been confirmed.

The guideline will be developed primarily for rheumatologists who care for patients with LN, but may also be used by other physicians and health professionals who care for these patients. The guideline will be developed in accordance with the ACR’s standardized approach, which includes use of the GRADE methodology. Overall, the guideline will conform to AGREE II criteria.[1] Details of the ACR’s guideline development methodology, processes and related timelines are available in the ACR Guideline Manual, which is posted on the ACR web site.

The ACR intends to partner with a team of individuals with clinical and methodological expertise and experience to develop this guideline. Letters of interest will be accepted from teams as well as from individuals who are not proposed as part of a team. Well-formed teams may be given preference over individuals, but the ACR will almost certainly decide to invite interested and qualified individuals to become part of the project team, even if they are not part of a proposed team.

The main focus of the letter of interest should be on the people who are proposed to partner with the ACR on this project, their qualifications for this work, and the particular roles for which they would be best suited. Project timeline and methodological and budget details do not need to be included. The successful letter of interest will:

1. Suggest a well-qualified, balanced guideline development group to assemble and review the evidence and determine the appropriate recommendations. The membership of the guideline development group will be broadly based, including rheumatologists, other physicians, specialists and health professionals who have particular needed expertise and/or care for patients with LN. Rheumatology private practitioners and academicians must be included. Preference will be given to individuals with expertise and experience in either guideline development or LN, or
both. Patient representatives will also be included (see page 8 of this document for additional information on patient involvement).

2. Divide the proposed guideline development group into the following sub-groups:

- **Core Leadership Team** of no more than 4-5 people, led by a principal investigator who will be accountable with ACR staff and committee volunteers for completion of the project according to a timeline and project plan that are finalized after the guideline development team is confirmed. Other members of the Core Leadership Team will include a literature review leader and the guideline panel leader, if the PI is not serving in this role (see below), as well as a GRADE expert who will be confirmed by the ACR. (NOTE: The ACR has worked with several GRADE experts on other guideline projects and can help fill this role.)

- **Literature Review Team** members, up to 4-5 people who will be led by a designated literature review leader who is part of the Core Leadership Team. The Literature Review Team will work with ACR and externally contracted staff to conduct the review of available evidence that will serve as the basis of the recommendations made in the guideline, according to the project timeline and schedule for deliverables. Lit review team members should ideally have demonstrated methodological expertise and experience doing systematic literature review work and be ready to perform the screening, data abstraction and data synthesis activities that are an integral part of any lit review. However, this is also an excellent place to include fellows who wish to contribute to the project and learn these skills, so the ACR welcomes suggestions of trainees for the lit review team.

NOTE: Because of the PI’s prominent role in development of the final guideline and the need for some separation between the literature review and the recommendation development processes, the project PI may not also lead the literature review.

Also NOTE: The ACR may choose to separately choose a literature review team and/or leader for this role, depending on the expertise and methodological background deemed necessary for this project. In this case, lit review team members who are proposed in letters of interest may be integrated into the overall guideline development team in other roles, or some may be named to the lit review team alongside ACR and/or contracted staff to perform the lit review work.
• **A Voting Panel** of approximately 10-12 people led by either the PI or another designated **guideline panel leader**, who is part of the Core Leadership Team. The Voting Panel will lead the decision process regarding the recommendations.

• **An Expert Group** of up to 15 people with LN expertise, who will participate early to help scope the project and develop the clinical questions that will be answered in the final guideline.

3. Include a complete disclosure of relationships for each person in the proposed guideline development group (see Application Procedures below), a commitment to follow the ACR disclosure and COI policies, and a summary of how the following ACR COI requirements are met in the proposed guideline development group composition:

• **At least 51% of the overall guideline development group** (i.e., anyone who is intellectually involved in the project) must have no conflicts of interest related to the subject of the guideline (**look back period is to November 30, 2017, one year prior to letter of interest deadline, and COI includes research funded by companies with an interest in the guideline topic**). **Similarly, at least 51% of the Literature Review Team and 51% of the Voting Panel must have no conflicts of interest related to the subject of the guideline.** NOTE: The 51% unconflicted threshold is a **minimum**; the ACR’s goal will be to have nearly 100%, or certainly significantly more than 51%, of unconflicted participants overall and on each smaller subgroup, if possible. Proposed teams should include as many unconflicted experts as possible to help facilitate this goal. Potential participants with conflicts are much more likely to be included in the expert group, as this group will help determine project scope and clinical questions but not the final recommendations.

• **The project PI must not have conflicts of interest related to the subject matter of the guideline** (**from November 30, 2018, through publication of the guideline, and for one year after publication**).

• **The literature review and voting panel leaders should also be unconflicted with regard to the subject matter of the guideline** (**from November 30, 2018, through publication of the guideline, and for one year after publication**).

Through these and other COI requirements that are outlined in the ACR Guideline Manual, the ACR’s intent is not to exclude investigators with potential conflicts from participating in this project, but rather, to manage such conflicts in a prospective, structured and reasonable manner to minimize the likelihood of inappropriate influence of such conflicts on guideline development. Specifically, the disclosure and COI policies and procedures are meant to deal with individuals’ conflicts that may potentially bias
how evidence is chosen, assembled, assessed and synthesized, or bias the recommendations based on such evidence. The description of strategies for managing conflicts of interest related to the specific agents and approaches used to treat LN will be explicitly laid out in the final guideline manuscript.

4. **Affirm a commitment to actively work with the ACR to complete the guideline within a 12-18 month time frame**, as specified in the project timeline, especially confirming the availability of each potential team member for a possible 1-day scoping meeting in May or June 2019 and each voting panelist for a 1.5-2-day mandatory voting panel meeting in April or May 2020. NOTE: Both meeting dates will be determined based on panelists’ availability, once the guideline development team has been confirmed; the location for both meetings will likely be Atlanta, GA. If a voting panelist cannot make the voting panel meeting date that is deemed best for the majority of the voting panel, that person may be removed from the voting panel.

5. **Affirm a commitment to keep all guideline deliberations and materials confidential until publication.** This includes a commitment by each person NOT to participate in other, non-ACR guideline or recommendation development efforts with similar topics until after publication of the ACR guideline.

6. **Agree to work with the ACR annually after guideline publication to review updated literature searches**, if requested by ACR, with a goal of evaluating the need for guideline revisions or complete updates. NOTE: This is not a requirement for an annual literature review update, but rather, a scan of the updated literature search(es) conducted by the ACR, to help the organization determine if a guideline update is warranted. See pages 23-25 of the ACR Guideline Manual for more details about this annual evaluation.

7. **Agree to work with the ACR to complete (an) interim update(s) as warranted by new developments in the field**, if requested and funded by the ACR.

**ELIGIBILITY REQUIREMENTS**

Letters of interest may be submitted by teams or individuals from domestic for-profit and nonprofit organizations, public or private, including but not limited to universities, colleges, hospitals, laboratories, and private practices. Collaborations that include individuals from multiple types of institutions/organizations are particularly encouraged. The ACR requires that private practitioners as well as academicians must be included in guideline development groups, to better reflect the intended audience for the final guideline. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators and members of guideline development groups.
Individuals whose primary employment is with the pharmaceutical, biotechnology or insurance industries are not eligible to apply or participate and should not be included in proposed guideline project development groups; “primary employment” is defined as 50 percent or more of an individual’s working time.

FUNDS AVAILABLE
The ACR will cover all project expenses directly; no other funding sources will be used to develop this guideline. The project budget may include some salary support or honoraria for either the project PI or the literature review leader; this support and the entire project budget will be discussed with the PI and literature review leaders at the time they are being confirmed. Salary support and indirect costs of up to 25% may be provided to organizations of lit review team members if a significant percentage of their time is spent on this project for a dedicated period of time (e.g., 6 months at nearly 100% effort). Additional funding will be separately provided for any future guideline updates.

ACR APPROVAL PROCESS, OWNERSHIP AND PUBLICATION OF GUIDELINE
- Following project completion, ACR staff and the project PI will submit the final report in the form of a manuscript to the ACR and its journals. The paper will be peer reviewed by expert reviewers and will be subjected to a formal ACR review process. The principal investigator will be responsible for any revisions required by the ACR or the reviewing journal.
- The final ACR Board-approved manuscript will be copyedited and published jointly in *Arthritis Care and Research* and *Arthritis and Rheumatology*. Authorship will be individual, but the guideline will be copyrighted by the ACR. Upon final approval by the ACR, the guideline will be known as the 2021 American College of Rheumatology Guideline for the Management Lupus Nephritis. The guideline, including any future updates, will be posted on the ACR website. The review process for any update(s) will be similar to that of the original guideline, unless changes are minor. The update(s) may also be published in *AC&R* and *A&R* according to the same process described above, which is described in more detail in the [ACR Guideline Manual](https://www.rheumatology.org/). Further details on the ACR policies and procedures re: practice guidelines can also be found in the manual.

APPLICATION PROCEDURES / GUIDANCE ABOUT DISCLOSURES
Standardized forms for the submission of letters of interest to the ACR are not provided. Letters over 10 pages will not be considered for evaluation. This page count should include but may not be limited to a complete list of investigators and personnel who are proposed to work on the project, a specification of the capacity in which each person could work (e.g., lit review team, voting panel), and a description of their relevant expertise and experience.
Two appendices are required outside of the 10-page limitation: 1) a curriculum vitae (CV) or NIH biosketch for each of the listed participants; and 2) a completed ACR disclosure form for each project development group member (i.e., anyone intellectually involved in the entire guideline development process). This is an essential part of the application; **individuals whose CV/biosketch and completed disclosure form are not received by the ACR by the November 30, 2018, deadline may not be considered.**

**Disclosures should include** relationships with commercial entities and insurance companies, as well as additional categories requested on the ACR disclosure form (e.g., primary employment, sources of personal income, intellectual property, research grants/contracts that involve and/or support the person disclosing, medical and non-medical industry investments, organizational benefit, activities with other organizations, including any current or anticipated similar guideline efforts, and relevant disclosure of first degree family members). Applicant disclosure information is shared with reviewers as the final project participants are being selected.

Although **full disclosure of relationships is required**, investigators should pay particular attention to relationships with the companies listed on the affected companies list for this project, or other companies not listed that have an interest in lupus, and clearly highlight on their disclosure forms any relationships they have with companies that have an interest in lupus, whether or not that is the subject of their relationship.

The ACR defines “affected companies” as those that are reasonably likely to be positively or negatively affected by care delivered in accordance with the guideline. *The above list is not meant to be all-inclusive, but rather, to provide guidance for individual disclosure; applicants who have relationships with other affected companies, as defined above, must disclose that information on their disclosure forms as well.*

**PIs of ACR guideline development projects must be free of conflicts of interest relevant to the subject matter of the project** for at least one year prior to the LOI deadline, through the project until publication, and they are expected to remain free of such conflict of interest for at least one year after publication. The ACR has the same expectation for the lit review leader.

The majority (at least 51 percent) of the guideline project development group must be free of conflicts of interest relevant to the subject matter of the project for at least one year prior to the LOI deadline and throughout the project until publication. This percentage must be maintained throughout the guideline development timeframe, until publication. This percentage is also applied separately to the Literature Review Team and the Voting Panel. As noted above, the ACR intends to populate the group with as many unconflicted participants as possible, while involving conflicted people as necessary to ensure that the group is sufficiently balanced with appropriate expertise and experience.
The conflict of interest thresholds will be based on an evaluation of relationships, primarily with affected companies. If a person has any relationship with an affected company, that person is counted as conflicted (toward the allowed threshold) regardless of the type or subject of the relationship.

An electronic copy of the final letter of interest should be e-mailed by November 30, 2018, to:
ACR Practice Guideline Subcommittee
c/o Regina Parker
American College of Rheumatology
2200 Lake Boulevard NE
Atlanta, GA 30319
rparker@rheumatology.org

Letters of interest not provided in electronic format will not be reviewed. Questions about the application process can be directed to Amy S. Turner (aturner@rheumatology.org) or Regina Parker (rparker@rheumatology.org).

Patient Volunteer Information and Form

for involvement in the

ACR Lupus Nephritis Guideline Project

The ACR develops clinical practice guidelines for use by physicians, health professionals, patients and other stakeholders who want to ensure high quality, evidence-based care for rheumatic disease patients. ACR guidelines include recommendations for using therapies that are available in the United States, advising on which work best in different clinical situations and patient groups. They are not meant to be prescriptive but to provide guidance based on the most recently published evidence about what helps patients the most without exposing them to unnecessary harms or risks.

Patients play an important role in the ACR’s guideline development work. Involving patients allows their views and experiences to complement both the published evidence and the expertise and experience of physicians, health professionals, and others who are part of the guideline development team.

Would you like to volunteer to work with the ACR to help develop guidelines that incorporate the values and preferences of LN patients?

If so, here’s what we would ask you to do:

• As part of the application process:
  o Submit an application to help us get to know you better
  o Verify that you are a patient with LN
  o If requested, participate in a brief phone interview to discuss your interest in more detail

• If you are confirmed to be involved:
  o Be a member of a group of 10-12 patients who will give feedback on the project scope (especially outcomes that are important to LN patients), examine the available evidence, provide patient perspectives on what the recommendations should be, and give input on additional questions from the guideline development team, if any
  o As part of this patient group,
    ▪ You will be asked to listen to an online orientation webinar in spring 2019 (1 hour total)
    ▪ You may be asked to actively participate in a possible 1-day face-to-face project scoping meeting in May or June 2019 (location to be determined, but likely Atlanta)
    ▪ You will be asked to provide online feedback on the drafted project scope in June or July 2019 (~1 hour)
    ▪ You will be asked to actively participate in a 1-day patient panel meeting in April or May 2020 (location to be determined, but likely Atlanta), where a group of patients will review summaries of the published research studies about management of LN and provide input into what the guideline recommendations should be
    ▪ You may be asked to actively participate in a 1.5 day voting panel meeting in April or May 2020 (location to be determined, but likely Atlanta) to review evidence and
provide input into the recommendations as part of the voting panel that will determine the final guideline recommendations.

What skills are required?
You will be trained for this role, but it would be helpful if you are enthusiastic and have good communication and teamwork skills. You also need to have time to commit to the work of the group during the timeframes listed above.

Costs/expenses
All travel and other out-of-pocket expenses related to your participation in this project, especially any face-to-face meetings, will be reimbursed (for example, costs of travel to and from the meeting(s), parking charges, and child care, if necessary). In addition, after the project is completed, if you have actively participated in all phases of the project to which you were invited (i.e., completed online orientation, provided scoping online input, attended face-to-face meeting(s), and responded to follow ups, if requested), you will receive $500 compensation for your participation.

What can you expect from the ACR?
- Appreciation and respect
- Support
- Relevant information and training opportunities

What training and support will you receive?
At minimum, all patients will be expected to listen to a 1-hour online orientation webinar that discusses the role of patients in guideline development. Patients who have been involved in previous ACR guideline projects have found this orientation to be helpful preparation for the face-to-face meeting discussions and decision-making.

The ACR staff and physician(s) who will facilitate the face-to-face meeting(s) will also be available before and after the meeting(s) for questions and orientation by phone and/or email, as needed.

Disclosure of relationships and confidentiality
The ACR asks everyone who is involved in ACR guideline projects to complete and sign the following forms:
- Disclosure of relationships – This form asks about your personal and non-personal interests in other organizations that might be doing work similar to the ACR, or commercial companies that might be, for example, involved in producing new drugs. We ask everyone who participates in ACR guideline work to act as independently as possible. If anyone has significant personal interests that may conflict with the ACR’s work, that person might not be considered to participate. This form must be completed and submitted with your application.
- Confidentiality – This agreement asks you to keep all project-related materials, discussions and decisions confidential until the guideline is approved by the ACR and publicly available through publication. You would be asked to complete this form if you are confirmed to participate in the project.

How should you apply?
You should complete the application form, which includes a short personal statement detailing your reasons for wishing to participate as a patient representative in this project. You should highlight any relevant skills and experience. The application, plus the other 2 items listed at the bottom of the application form, must be emailed to Regina Parker at rparkerrheumatology.org, no later than Friday, November 30, 2018.

When will applications be considered, and when will decisions be made?
All applications will be immediately considered by the ACR. Each short-listed nominee may be invited to schedule a phone interview by March 2019, and final decisions will be made immediately thereafter. All applicants will be notified of their status by email by early April 2019.

**When will orientation and training happen?**
Participants will be expected to participate in a 1-hour orientation webinar in spring 2019, at whatever time of day they choose. Additional orientation may also take place during the face-to-face meeting(s).

**Who may I contact with questions about the application process or this project?**
Please email ACR staff Regina Parker at rparker@rheumatology.org or call her at 404-633-3777, ext. 822. Alternatively, you may also email ACR staff Amy S. Turner at aturner@rheumatology.org or call her at 404-633-3777, ext. 813.
APPLICATION FORM

Please complete this form to apply to be a patient representative to the 2019-2020 ACR LN Guideline project. If you have any questions or concerns about the form, please call ACR staff Regina Parker at 404-633-3777, ext. 822, or email her at rparker@rheumatology.org.

Contact details

Full name: ___________________________________________________________________________

Address: _____________________________________________________________________________

Phone number (preferred): ______________________________________________________________

Phone number (alternate): ______________________________________________________________

Email address: ________________________________________________________________________

Please initial here to indicate that you would be able to listen to a 1 hour orientation webinar in spring 2019 (at whatever time of day you choose).

Please initial here to indicate that you would be willing to actively participate in a 1 day face-to-face project scoping meeting in May or June 2019, if requested, pending calendar verification (meeting date and location to be determined, but likely in Atlanta).

Please initial here to indicate that you would be able to provide online feedback on the drafted project scope in July 2019 (~1 hour).

Please initial here to indicate that you would be willing to actively participate in a 1 day patient panel meeting and/or a 1.5 day face-to-face voting panel meeting in April or May 2020, if requested, pending calendar verification (meeting date and location to be determined, but likely in Atlanta).

Personal statement

(Please detail your reasons for wishing to participate as a patient representative in this project, and list any relevant skills and experience.)

Please return the following to ACR staff Regina Parker (rparker@rheumatology.org) by November 30, 2018:

1. This completed application form.
2. A written statement, signed by your physician, verifying that you are a patient with LN.
3. A completed ACR disclosure form.