

AMERICAN COLLEGE OF RHEUMATOLOGY
Policy and Procedure Manual
for Clinical Practice Guidelines
(January 2015)

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Purpose of this Manual

This manual is intended to assist guideline project development groups, including guideline panel members, with information on American College of Rheumatology (ACR) processes, policies, and methodology to help them in their work of developing guidelines that will improve the care of patients with rheumatic diseases.

ACR Resources

The ACR seeks to partner with Principal Investigators (PIs)* and guideline project development groups to produce high-quality guidelines that meet expectations regarding methodology, timeline, budget and deliverables agreed upon by the ACR and PIs before projects begin. To facilitate this outcome, the ACR provides project support in the following areas, at levels agreed between PIs and the ACR before the start of each project:

- Project funding
- Content, methodology and process expertise, as needed
- Literature searching, study identification and reference management
- Assistance with the evidence review, as resources permit
- Administrative assistance with logistical details of projects (e.g., meeting planning, conference call/webinar scheduling, communication assistance, and handling direct payments related to meetings, calls and panel stipends or travel expenses)
- Assistance with disclosure and conflict of interest requirements

* **Guideline Project Development Group:** includes anyone intellectually involved in the development of ACR guidelines. Includes, but is not limited to, guideline panel members.

Guideline Panel Members: individuals in a guideline project development group who are usually responsible for analyzing available evidence and voting on the final recommendations.

Principal Investigator or PI: the individual who leads an ACR guideline development project.

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Guideline Development, Phase 1: Preparation

Priority Setting

Rheumatoid arthritis, osteoarthritis, and osteoporosis are guideline topics for which the ACR plans to maintain an ongoing commitment. Other guidelines will be developed, as necessary, based on known gaps in care and developments in the field, as resources for such development are available. The ACR may partner with other organizations, as appropriate, in setting priorities in areas of common interest, and possibly working jointly on systematic literature reviews.

Recommendation of Topics / Project and Funding Approval

The ACR Guidelines Subcommittee recommends topic(s) to the ACR Committee on Quality of Care (QOC), based partly on periodic needs assessments of the ACR membership, the broader rheumatology community, and/or ACR leadership. Members are solicited for guideline topics via annual broadcast e-mail solicitations with links to the ACR website, where the topic submission form is available (see Appendix 1 for form).

All topic suggestions are considered at the fall Guideline Subcommittee meeting, and decisions are made about which topics to recommend to QOC for inclusion in the next year's budget. Needs assessments are considered in the context of Guideline Subcommittee members' knowledge and investigation of discussed topics, as well as known topics of concern in rheumatologic care.

Each January, the QOC considers the Guideline Subcommittee's proposed topics as part of its normal budgetary process and makes a decision about recommending proposed topics to the ACR Board of Directors for funding approval. If the QOC desires possible involvement of another organization in either the guideline development or approval process, the QOC requests Board approval of that relationship at the time of project approval so the relationship can be initiated and its parameters established before the project begins. If the partner's process, timeline and/or forms are different from ACR's, the ACR may decide to adopt the partner's processes to accommodate the partner's preferences or requirements.

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Call for Letters of Interest

Once a guideline topic has been approved and funded by the ACR Board of Directors, the Guideline Subcommittee develops a Call for Letters of Interest (LOI). The LOI, project timeline, ACR disclosure form and a link to the ACR Guideline Manual are posted together on the ACR website and distributed electronically to the ACR membership. The Call for LOI will include the guideline purpose, scope, audience, budget, and timeline, an explanation of the research methods to be used for guideline development, and a list of “affected companies.” (See below for explanation of affected companies. See Appendix 2 for Call for LOI template, Appendix 3 for guideline development timeline, and Appendix 4 for ACR disclosure form).

If the ACR plans to partner with an outside group to perform the systematic review, which is the foundation for recommendations, this information will be included in the Call for LOI.

Rarely, if warranted by issues of importance, timing or other extenuating circumstances, the ACR may decide to proceed with a guideline development project without distributing a Call for LOI.

Eligible Applicants

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 project development groups. Individuals whose primary employment is with the pharmaceutical, biotechnology or insurance industries are not eligible to apply 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.

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As noted above, 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 will be given preference over individuals, but the ACR may decide to invite an interested and qualified individual to become part of the ACR 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.

Composition of the Guideline Project Development Group

Membership of the group should be broadly based. It must include:

- Rheumatologists, other physicians, specialists and health professionals who care for patients with the target disease
- Private practitioners as well as academicians
- At least one clinician or clinical epidemiologist with significant GRADE methodology expertise and experience
- At least one person with expertise in biostatistics
- Knowledgeable consumers and patient advocates (at least one of each)

A **Core Leadership Team** of no more than 4-5 people will be confirmed to lead the work of the project with ACR staff. At minimum, this team will include 1) a project PI, who will be primarily accountable with ACR staff for the completion of the work according to the agreed upon project plan and timeline; 2) a literature review leader (unless it is being done by or with an outside group); 3) a guideline panel leader, who will lead the decision process regarding the recommendations; and 4) a GRADE expert. The project PI may also serve as the guideline panel leader. However, because of the PI's prominent role in the development of the final guidelines and the need for some separation between the systematic review and the guideline recommendation development processes, the project PI may not also lead the systematic review. The GRADE expert does not have to be a separate person, if one of the other Core Leadership Team members has significant GRADE expertise and experience and plans to advise the group on GRADE methodology and hold them accountable throughout the project.

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A **Literature Review Team** of approximately 4-5 people will conduct the review of available evidence that will serve as the basis of the recommendations made in the guideline.

A **Voting Panel** of approximately 10-12 people will lead the decision process regarding the recommendations.

Other experts will be added to the guideline development group, as needed.

Disclosure of Relationships / Conflict of Interest

ACR Requires Full Disclosure of All Relationships, not just Potential Conflicts of Interest

Applicants must fully disclose their relationships at the time of application, using the ACR disclosure form (see Appendix 4). A completed ACR disclosure form must be included for anyone who will be intellectually involved in the guideline development project. Each form should list all relationships, including recent (i.e., within 1 year before proposal deadline), existing, and planned (i.e., known at the time the form is completed but not yet begun).

When developing a Call for LOI, the ACR proactively identifies companies and organizations that may be affected by the work. This “affected companies” list includes but is not limited to pharmaceutical, biotechnology, or other companies that manufacture or market products or therapies that might be affected by the ACR’s work, or competitors of these companies. Affected companies are ones that are reasonably likely to be positively or negatively affected by care delivered in accordance with the guideline. The list of affected companies is included in the Call for Letters of Interest, with a requirement that disclosures related to these entities must be explicitly included in the written disclosures submitted as part of the letter of interest. Note that the affected companies list provided by the ACR 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 also explicitly disclose that information.

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Managing Conflict of Interest

PIs of guideline development projects are expected to be free of conflicts of interest (COI) relevant to the subject matter of the project for at least one year prior to LOI deadline, throughout the project until publication, and they are expected to remain free of such conflict of interest for at least one year after publication. The literature review leader is held to these same expectations.

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. Similarly, at least 51% of the Literature Review Team and at least 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 significantly more than 51% unconflicted participants overall and on each smaller subgroup to allow for unanticipated mid-project personnel shifts (e.g., a participant drops out due to illness or schedule changes).

The conflict of interest thresholds will be based on an evaluation of relationships, primarily with affected companies. Unless their relationship completely excludes them from participation (e.g., industry employment), a person who has any relationship with an affected company is counted as conflicted (toward the allowed threshold) regardless of the type or subject of the relationship. Finally, although intellectual conflicts of interest are important and should be disclosed, they are ubiquitous and, therefore, the ACR does not count someone with intellectual COI as conflicted (toward the allowed threshold) based on the intellectual conflict alone.

Intent of ACR disclosure/COI policies

The intent of ACR disclosure/COI policies is not to exclude all investigators with potential conflicts from participating in the project, but 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 ACR's 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 related to the specific agents and approaches used to treat the target disease will be

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explicitly laid out in the final manuscript. This process and information will be considered in the review process. (See disclosure/COI Policy section of ACR QOC policy, Appendix 5, and disclosure/COI section of this manual below).

Funding

In general, the ACR funds its guideline development efforts without outside financial support. However, if topic priorities and development methodologies are similar, the ACR will consider partnering with another medical professional organization or other guideline developer, in which case funding from this other organization may be acceptable. In this situation, the other organization's funding contribution must not come from industry or any other funding source the ACR would not use for its own guideline efforts. In kind support is accepted only from these partner organizations or other groups with which the ACR agrees to collaborate to conduct systematic reviews (e.g., ARHQ).

The amount of funding ACR will provide for each project is approved before the project begins. The ACR covers all project expenses directly. The project budget may include some salary support or honoraria for either the project PI or the literature review leader, or possibly data abstractors involved in the literature review. This support and the entire project budget are discussed with the PI and literature review leader at the time they are being confirmed. The project budget may also include honoraria for members of the literature review team/leadership and the voting panel to acknowledge their efforts and time spent on this activity, and possibly other consultants deemed necessary for the successful completion of the project. 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). (See Appendix 6 for the ACR's Indirect Cost Policy.) Additional funding will be separately provided for any future guideline updates.

If the ACR is working with an outside group to conduct the systematic review, the funding timeline will be altered, as needed, to accommodate both the ACR's and the outside group's needs. In either case, however, the funding timeline and related deliverables will be set and agreed upon by all parties before the guideline development process begins.

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Project Timeline

The overall timeline for the development of ACR guidelines through this process is approximately 15 months from the beginning of Phase 2 – Development (i.e., convening of the systematic review team – see below for more details) until ACR approval of the final guideline manuscript. This is a tight timeline and requires vigilant oversight on the part of the project PI, the systematic review leader, the guideline panel leader (if not the project PI), and the ACR. Team members involved in all processes are expected to adhere to deadlines.

The major timeline milestones are 1) confirmation of the PI and guideline development team; 2) development and finalization of the protocol; 3) completion of the systematic review; 4) development of GRADE evidence profiles and vote on recommendations; 5) guideline drafts; and 6) joint publication of the guideline in *Arthritis Care & Research*, *Arthritis & Rheumatism*, and on the ACR website. (See Appendix 3 for a more detailed project timeline).

For guidelines that are developed based on a systematic review produced by a group with which the ACR is partnering, timelines may differ.

Letters of Interest / Application Deadlines

Letters of interest (LOI) are due no more than 8-12 weeks after the Call for LOI is posted. Letters must include all required elements listed in the Call for LOI, including completed disclosure forms for everyone who will be intellectually involved in the guideline development. Incomplete or late letters of interest may not be reviewed.

Letter of Interest Procedure

Standardized forms for the submission of LOIs 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 might best work (e.g., literature review team, voting panel), and a description of their relevant expertise and experience.

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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; **applications that do not include a CV/biosketch and a completed disclosure form for all intellectually involved persons will not be considered.**

A master copy of the ACR disclosure form can be found in Appendix 4.

Proposal Review

ACR staff initially reviews all letters to ensure they are complete and in compliance with basic ACR policies (e.g., all CVs and disclosure forms are included, a suggested PI has no COI, etc.).

LOIs that pass this initial staff review are then submitted for consideration by the Guideline Subcommittee as they determine the final guideline development team. The subcommittee's decision making includes evaluation of the proposed PI and guideline development group members' training and experience, diversity, capacity, and anticipated group dynamics. The subcommittee may combine interested participants in different ways than were proposed in the letters of interest, including combining members of proposed teams. The subcommittee may also include people whose names were not received in response to the Call for LOI.

The ACR Guideline Subcommittee then makes a recommendation to the ACR Quality of Care Committee about who should make up the guideline development team, and what their roles should be. The final decision about the makeup of the guideline development team is determined by QOC vote. This decision is then conveyed to all who submitted letters of interest.

Confirmation of PI / Literature Review Leader/ Guideline Project Development Group and Initial Funding

Once the project PI and literature review leader have been confirmed, ACR staff negotiates financial / logistical details with them and confirms an ACR Board liaison and a Quality Measures Subcommittee liaison for the project. ACR staff also confirms with the PI and lit review leader the other members of the

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project's Core Oversight Team. Once verbal agreements have been made on these issues, ACR staff sends all Core Team members, including the PI and lit review leader, a written letter of agreement, a list of agreed upon deliverables and responsibilities, and a detailed timeline, for individual and, if necessary, institutional approval and signature. (See Appendices 3, 7, and 8 for explanation of the ACR Board liaison, ACR Quality Measures Subcommittee liaison, letter of agreement, list of deliverables / responsibilities, and guideline development timeline).

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Guideline Development, Phase 2: Development

Accountability

ACR staff, committees, PI and other members of the guideline project development group (including the systematic review team and guideline panel) have specific responsibilities for which each is held accountable over the course of the project (see Appendix 7). Among other responsibilities, PIs are expected to work with the ACR to confirm project timelines, milestones, deliverables, and related funding details in writing before the project begins.

The ACR staff will provide oversight of the project in partnership with the PI and Core Team. Staff will also provide administrative assistance with logistical details of the project (e.g., meeting planning, conference call scheduling, communication assistance, and/or handling direct payments related to meetings, calls/webinars and panel stipends or travel expenses); provide assistance with disclosure and COI requirements; and potentially assist with literature searching and associated functions, as required by the project and as ACR resources permit. The ACR staff and committee volunteers will also provide process and methodology expertise, and content expertise, as needed.

An organizational conference call between the PI, Core Team, ACR Board liaison, and ACR staff will be scheduled by ACR staff at the outset of the project to ensure that everyone understands his or her roles and responsibilities.

Use of GRADE to Evaluate the Evidence and Develop Recommendations

Beginning in late 2011, the ACR will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology for all *new* guideline development projects, including systematic reviews of evidence and guideline recommendations. Information about GRADE may be found online at <http://www.gradeworkinggroup.org/>, including a 20-part guide on GRADE from the Journal of Clinical Epidemiology. In addition, several useful articles are included in the reference list.[1-14]

GRADE provides a transparent, systematic and explicit approach to the development of recommendations, which are characterized as either strong or conditional and are based on evidence,

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the quality of which is assessed as high, moderate, low, or very low. GRADE makes a clear distinction between quality of evidence and strength of recommendations.[2] Other factors, such as patient and clinician preferences and values, are also taken into consideration and are explicitly stated in the guideline recommendations.[1] The GRADE system helps guideline development groups make decisions about quality of evidence and strength of recommendations in a systematic and transparent manner, but does not eliminate the need for judgments. [12]

Initial Project Planning: Protocol Development and Approval

A systematic literature review is used as the basis for development of the recommendations within all ACR guidelines. The systematic review is based on a project protocol (i.e., project plan) that is developed by the project PI, systematic review team leader, and the rest of the Core Team, as well as selected project participants (including the systematic review team and the leader of the guideline panel, if the project PI is not also serving in this role), in conjunction with the ACR. In addition to serving as the basis for the literature review, the protocol guides project leaders and participants as they work to accomplish the goals and objectives of the project. The protocol is essential to minimize bias[15] and to ensure that the end product(s) delivered meet the needs of the ACR membership and the original intent of the project. The protocol will address broad specifications for the project, as well as the detailed information related to the systematic review. (See below for more details of what will be included in the project protocol and Appendix 8 for the ACR protocol template.)

Development of Clinical Research Questions / PICO Questions

Specific clinical questions need to be answered in the systematic review, and the literature search strategy is based on these questions. The “PICO” format informs the key questions/clinical questions being asked. The acronym PICO stands for **P**opulation (condition(s), patient, or problem being addressed); **I**nterventions (e.g., treatment), **C**omparator (alternative intervention for comparison), and **O**utcomes (clinical outcomes of interest).[11] Important and critical outcomes should be the focus[11], i.e., as defined by patient or clinician, rather than those driven by available evidence. In addition to PICO, pre-specified types of studies are included as part of the criteria for the systematic review development. Sometimes the setting is also an important aspect of the question. The systematic review leader and team, with input from the project PI and the guideline panel leader, develop PICO

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questions for each guideline project using a consensus process involving the Guideline Subcommittee, an adequately representative sample of clinicians, and the patient/consumer representative(s). Once the clinical questions have been developed, they are included in the project protocol for ACR approval and subsequent public comment via the online feedback mechanism described below.

An example of a question framed according to PICO format is: “Are balance exercises effective in reducing pain and improving function in patients with symptomatic knee OA compared to strengthening exercises?” The population is patients with symptomatic knee OA, the intervention is balance exercises, the comparator is strengthening exercises, and the outcomes are pain reduction and improved function.

Other Details included in the Protocol

The protocol will also include how studies will be identified (and include an electronic strategy for Medline/PubMed search with a notation that the search will be modified for other named databases, and how and if gray literature will be identified), inclusion and exclusion criteria for studies, information about quality assessment, and *a priori* specification, for example, about how to deal with such methodological issues as heterogeneity.

Final Approval of the Protocol / Public Comments

The protocol will be submitted to the ACR Guideline Subcommittee for final approval before the systematic review is conducted. In addition, the project protocol will be posted on the ACR web site for public comment. Feedback received will be considered as the systematic review begins. If warranted, the systematic review team, PI and ACR may decide to modify the protocol as a result of this evaluation. Responses received during the public comment period will be posted online with the final guideline manuscript, including each respondent’s name, professional affiliation, city/state, and disclosure. NOTE: To facilitate meeting major project milestones, the early stages of the literature review (i.e., searching) may occur simultaneous to the Guideline Subcommittee review / public comment period, with modifications made to the searches, if needed, in response to the review comments.

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Use of Existing, Current Systematic Reviews

As a general rule, ACR guidelines will be based on systematic reviews that are performed as part of the ACR guideline development process. However, in order to reduce duplication of effort, it may be determined that existing, current systematic reviews or meta-analyses that address the questions of interest to the ACR/guideline developers can be used in the ACR guideline project. These exceptions must be approved in advance by the ACR, and these systematic reviews will be quality-assessed, for instance with use of the AMSTAR tool.[16] The Guideline Subcommittee reviews the recommendations for use of certain systematic reviews in the project, along with the quality assessment of each systematic review, before conveying its final approval to the guideline developers.

Output of Systematic Review / Drafting Recommendations

The systematic review team compiles output from the systematic review to help inform the drafting of recommendations. This information takes the form of Evidence Profiles that provide simple, transparent summaries of the quality of evaluated studies and their findings relevant to the outcomes being examined in the guideline. The Summary of Findings information includes a qualification of the quality of evidence as very low, low, moderate or high, based on several factors explicitly outlined in the GRADE methodology.

Once this work has been completed by the systematic review team, each guideline panel member is asked to consider the quality of available evidence, judge the balance between desirable and undesirable effects, consider patient / clinician values and preferences as well as resource allocation (i.e., cost), and determine what type and strength of recommendations should be made. The strength of the recommendations is categorized as either “strong” or “conditional.”[9] Typically, if panel members are very certain that benefits do, or do not, outweigh risks and burdens, they will make a strong recommendation. If panel members decide that benefits and risks/burdens are balanced, and/or considerable uncertainty exists about the magnitude of benefits and risks, they may make a conditional recommendation.[7] In addition, when panel members believe that fully informed patients are likely to make different choices based on their own values and preferences despite strong evidence, they will likely offer a conditional recommendation.[7, 17]

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Guideline Panel Voting

The guideline panel members will then vote on guideline recommendations, and the voting scores will be included in the supporting information that is posted online alongside the final guideline document. Sometimes there may be little published high quality evidence on outcomes of interest. When there is no strong evidence and expert opinion is more heavily required when formulating a recommendation, this will be transparently presented both in the guideline development process and the final guideline paper. This is an opportunity to help influence the research agenda for work on the outcome in question.

Finalizing the Guideline Recommendations

Detailed recommendation tables will be developed and will include the voting results of the guideline panel members for 1) each proposed recommendation statement; 2) the overall quality of the evidence related to that recommendation; and 3) the strength of the recommendation (i.e., strong or conditional). In addition, underlying values and preferences of members of the guideline panel should be included, if possible, as well as other clinical notes and context to assist with the interpretation and application of the recommendation, as appropriate. Recommendations will be synthesized into a final guideline document for publication in *Arthritis Care & Research* and *Arthritis & Rheumatism* (see below and Appendix 9 for formatting details).

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Guideline Development, Phase 3: Approval, Publication, and Dissemination

Authorship

If the guideline development team was assembled by the ACR, using an objective process to ensure adequate balance and expertise, authorship is individual and the project PI will be the first author. Although it is ACR policy that the PI will be first author, the ACR expects the PI to do the requisite work to justify the first authorship position (e.g., lead the project and draft the final guideline paper). The PI is responsible for making other authorship decisions (i.e., who is an author and what is the appropriate author order), using the guidance of the International Committee of Medical Journal Editors.[18] On the rare occasions an objective process is *not* used to determine who will participate on the guideline development team, authorship must be corporate unless an exception is approved by both the ACR and *Arthritis Care & Research* and *Arthritis & Rheumatism*.

Guideline Content and Design Formatting

To make ACR guidelines consistently of high quality, easy to use and more easily identifiable to users, a standardized template will be used for ACR guideline papers that are products of ACR guideline projects started after 2011. The template includes certain sections and language that must be included in every ACR guideline (see Appendix 9 for details).

ACR Approval, Copyright, Journal Approval and Publication

ACR funding or participation does not imply or guarantee ACR approval of the final publication or product of the project. To obtain ACR approval, guidelines must be formally reviewed by the ACR and approved by the ACR Board of Directors. Similarly, ACR approval does not imply journal approval, which involves a separate but concurrent review process.

PIs are asked to share a draft of the near-final guideline paper with the ACR Guideline Subcommittee chair and staff liaison to the guideline project development group before submission for journal or ACR approval. The subcommittee chair / staff liaison will examine the paper with organizational policies and high-level project goals in mind and provide any relevant feedback to the PI. The authors are required to respond to this feedback with related manuscript revisions; if PIs disagree with the feedback and do not

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wish to make requested revisions, they should discuss this with the subcommittee chair/staff liaison until consensus can be reached.

Arthritis Care & Research and *Arthritis and Rheumatology* have the right of first refusal for all ACR guidelines. Beginning with manuscripts approved after February 2013, ACR guidelines are jointly published in *AC&R* and *A&R*, with the journal reviews being overseen by one or the other journal on an alternating basis. Once the initial informal staff/subcommittee chair review is complete, the PI or staff liaison will submit the paper to either *Arthritis Care & Research* or *Arthritis & Rheumatism*, as directed by ACR staff, with a notation in the cover letter that the paper is the product of an ACR-funded project and, therefore, ACR approval is desired. If the PI submits the paper, the PI should also submit a copy of the submitted paper to the ACR staff liaison to facilitate the ACR review.

Concurrent journal and ACR review processes are followed, with periodic requests for manuscript revisions. Authors are expected to respond in a timely manner to these requests so review and approval processes can be completed as soon as possible.

The ACR reviews guidelines for approval using standardized processes and templates, against pre-determined review criteria. Manuscripts or other submitted documents are subjected to multiple levels of review by subject area and methodological experts. The ACR and the journals make independent review and approval decisions, although at certain points the administrative processes overlap for purposes of efficiency. The ACR reassesses its review process, as needed, to promote high quality publications, editorial independence, and timely publication.

Standard journal manuscript limits apply, with exceptions granted at the discretion of the journal editors. Supporting information, as outlined in Appendix 9, should also be submitted (e.g., evidence reports, tables, search strategies, detailed recommendations including GRADE evidence profiles and voting results). This information is not peer reviewed in the same way as the manuscript but will be posted online alongside the published guideline paper, on both the ACR and journal sites.

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The concurrent journal and ACR review process is conducted as follows, and takes approximately 2-4 months, depending on extent and timeliness of necessary revisions and the timing of ACR committee/Board meetings:

1. JOURNAL PEER REVIEW: Immediately after submission, the journal peer review is conducted by anonymous reviewers.
2. DISCLOSURES FOR ACR: Meanwhile, authors update their ACR disclosure forms and submit them to ACR staff. As described elsewhere in this manual, full disclosure of relationships is required, not just “relevant” disclosure. An ACR staff member summarizes the author disclosures in a 1-page document that will accompany the manuscript at each stage of ACR review.
3. ACR GUIDELINE SUBCOMMITTEE REVIEW: After they are complete, the journal editor sends the journal peer reviews to ACR staff, who forwards them along with the submitted manuscript and author disclosure summary to the Guideline Subcommittee for review. The subcommittee chair, with the assistance of ACR staff, reviews and summarizes subcommittee members’ comments into one cohesive subcommittee review. The chair also ensures that the subcommittee review either does not conflict with the journal reviews or provides direction to the author about how to handle conflicting reviews. Depending on the extent of the journal and ACR review comments, manuscript revision may be requested before the next stage of ACR review. If revisions are made, they are reviewed and approved by the subcommittee before the paper is sent to the Quality of Care Committee and Board of Directors for review.
4. A NOTE ABOUT DISCLOSURES: At the time the *revised* article is submitted to the journal, the journal will require authors to submit completed author disclosure forms online. To meet this requirement, authors must use journal disclosure forms, not the ACR forms they completed for the ACR review. The reason for this is that ACR and journal disclosure requirements are different. ACR requires disclosure of all relationships, whereas the journals require only “relevant” disclosure.

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5. ACR QUALITY OF CARE COMMITTEE and ACR BOARD OF DIRECTORS REVIEW: Once approved by the Guideline Subcommittee, ACR staff forwards the manuscript, the subcommittee and journal reviews, and the list of ACR author disclosures to the Quality of Care Committee for review. The QOC has the option to ask for additional revisions before the paper goes to the Board, but often it does not. Once approved by QOC, the final, revised guideline will be recommended to the ACR Board for approval. Board review may be by e-mail vote (requires 100% vote, and all votes in favor of approval) or wait until a phone or face-to-face Board meeting to obtain the approval (requires a majority of votes in favor of approval, of those present, if a quorum is present).

6. FINAL MANUSCRIPT REVISION AND RESUBMISSION to the ACR journal overseeing the review: If any revisions are requested by the QOC or Board that have not yet been made, these final revisions are done and the revised paper is resubmitted to the journal for final approval. The manuscript is usually published about 4 months after final approval is given by *both* ACR and the journals, although online e-publication of the final, edited manuscript may be achieved sooner and will be the ACR's goal, if possible.

Copyright and Title

The guidelines will be copyrighted by the ACR. Upon final approval by the ACR, the recommendations will be known as the ACR [*name of guideline*]. The guidelines, including any interim updates, will also be published on the ACR website. The review and publication process for an interim update will be similar to that of the original guideline. The interim update may also be published in *AC&R and A&R* according to the same process described above, at the discretion of the ACR and its journals.

Dissemination

After guidelines have been approved by ACR and the journals and a final copyedited draft has been produced, a Clinician's Guide, pocket guide, or web application may be developed by the PI in conjunction with ACR staff (and the Guideline Subcommittee, as needed). These tools are posted on the ACR web site alongside the new guideline as soon as it is published. Their purpose is to provide easy to use references for busy clinicians to remember the key points in the guideline. They are not meant as

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stand-alone documents that could be used in lieu of the full guideline. Other means of disseminating the guidelines are evaluated and may be pursued by the ACR, as resources and opportunities are available.

Public Comment on Guideline Document

Immediately after publication, the ACR will request public comment on the guideline via an online mechanism. Feedback received will be carefully evaluated and used to inform the next update or full revision of the guideline (see next section for more details on review and updating ACR guidelines).

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Guideline Development, Phase 4: Ongoing Review, Revision and Updating of Published Guidelines

Guidelines can become outdated for a number of reasons, including new studies that report on major or invalidating new evidence, and changes in practice. The ACR's goal is to inform clinicians of changes in research, which will sometimes require the development of completely new guidelines or changes to some recommendations within already published guidelines. ACR funds are allocated and approved for this work, as needed. The decision to update a guideline will be based on sound evaluation and empirical research in order to minimize unnecessary use of resources and time.

Updated Literature Searches

ACR staff update literature searches periodically and post the results on the ACR website; the goal is to do this quarterly but sometimes it happens at different intervals to serve the needs of the ACR. The information will include bibliographic references and links to abstracts, if the relevant abstracts are freely available. The goals of this exercise are 1) to help guideline users stay up-to-date on the current relevant literature on the guideline topics; and 2) to help the ACR determine whether a guideline update is needed, and if so, which form the update will take. Using these updated literature search results, including abstracts, the ACR Guideline Subcommittee and staff, with the option of input from experts and/or the guideline PI, will perform an initial screening of the studies based on the inclusion/exclusion criteria of the systematic review for the original or latest version of the guideline, to determine whether or not an update is needed.

Signals for Updating Clinical Practice Guidelines*

At least once every 2 years, the ACR will review any public comments received via the ACR web mechanism re: each published guideline and the information resulting from the updated literature searches. The goal of this evaluation is to decide if there is a need to update either the entire guideline or some recommendations within the guideline. The ACR looks for major or potentially invalidating changes in evidence. Examples include:

- a. At least one new high-quality, randomized controlled trial (RCT) with a population at least twice or three times the size of the largest RCT cited in the guideline

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- b. At least one new meta-analysis with one new trial not considered in the existing guideline
- c. RCTs, where before recommendations were based on cohort studies

If any of the following applies, it is likely that a recommendation update would be warranted:

1. Potentially invalidating changes in evidence
 - a. Opposing Findings: New evidence suggests conclusions opposite to those underlying current recommendations
 - b. Substantial Harm: New evidence suggests that the intervention would no longer be recommended due to substantial harm
 - c. Superior New Treatment: New evidence suggest that another intervention is significantly superior, based on efficacy or harm, such that it would be preferred in most settings
2. Major change in evidence: Recommendation is still essentially valid, but new evidence clearly has the potential to affect clinical decision making
 - a. Important changes in effectiveness, but not opposing findings: new evidence suggests that the benefit is greater or less than reflected in the current recommendations
 - b. Expansion of treatment
 - c. Important Caveat: New evidence suggests an important caveat about the patient population who may benefit, way in which treatment has to be delivered, sustainability of benefit, or increases in harm not sufficient to undermine use altogether but that would affect the decision to recommend the intervention for at least some patient populations.

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Options for ACR action following evaluation of the evidence[^]

NO NEW EVIDENCE: Publish an update on the ACR website, with a notice in *Arthritis Care & Research* and *Arthritis and Rheumatology*. In addition, insert a notation within the most recent version of the guideline paper published online, referring to the update that is now available on the ACR website. In the update on the ACR website, report the search strategy for the updated literature search and the ACR review process, including dates and number of abstracts / studies reviewed, and indicate that no new evidence has been identified and thus no changes were made to the recommendations. This update will be developed by the Guideline Subcommittee and ACR staff, possibly in conjunction with the guideline PI and/or other experts. The Board of Directors does not need to approve the update.

NEW EVIDENCE, BUT NO CHANGE TO RECOMMENDATIONS: Same e-update approach as above, with summary of updated search and review, plus identification of references for new evidence within the update posted on the ACR web site. The Board of Directors does not need to approve the update. Same approval process as above.

The QOC will provide an annual verbal report to the ACR Board of Directors on updates for the above two options.

NEW EVIDENCE, AND RECOMMENDATIONS CHANGE: The regular ACR guideline development, review and approval processes are used, and the updated guideline is published in *Arthritis Care & Research* and *Arthritis and Rheumatology* and posted on the ACR website.

For drugs or other therapies that have been withdrawn (e.g., due to harm), a notice is appended to the guideline on the ACR website, a notice is printed in *Arthritis Care & Research* and *Arthritis and Rheumatology*, and if possible, this notice is linked to the guideline published online at *Arthritis Care & Research* and *Arthritis and Rheumatology*.

In these cases, the Board of Directors will formally review the changes based on the new evidence and approval by the Board of Directors will be required.

[^]Options for ACR action following the evaluation of evidence: Adapted, and reprinted with permission. (c) 2011. American Society of Clinical Oncology. All rights reserved.

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Guideline Development: Disclosure and Conflicts of Interest**

The intent of disclosure of relationships, including but not limited to any potential conflict of interest, is to ensure that ACR guidelines are balanced, independent, objective, and scientifically rigorous. The ACR requires each guideline project development group member and others who contribute intellectually to the guideline development effort to disclose all information regarding their relationships, including any possible conflict of interest, financial or otherwise.

Activities related to the Committee on Quality of Care and its subcommittees, including the Guideline Subcommittee, should be free from actual or perceived industry influence. Therefore, the ACR does not utilize external support from commercial entities and insurers/health plans for activities of the QOC or its subcommittees. In addition, the QOC does not review quality-related products for ACR approval if industry funding was used to support their development. On a case-by-case basis, support may be considered for dissemination materials or strategies.

Disclosure of relationships and management of potential or real conflicts of interest are important at every level of the QOC's work, from prioritizing topics and selecting projects, through development and ACR approval of final papers.

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Committee on Quality of Care (QOC) / Subcommittee Disclosure and Management of COI

The QOC and its subcommittees, including the Guideline Subcommittee, are guided by two main principles related to disclosure and management of conflicts of interest. One relates to general discussions and decisions, and the other is more specific to particular projects.

- Members of QOC and its subcommittees should not influence policy decisions based on their relationships with outside organizations, and members should be aware of each other's relationships. Therefore:
 - QOC members provide written disclosures once each year and update these disclosures as needed during the year. They also verbally disclose at the start of every face-to-face meeting. The QOC chair receives copies of the written disclosures annually for review.
 - QOC subcommittees also disclose verbally at the start of every meeting.
 - Members recuse themselves from any discussions where a potential COI or the appearance of COI exists.

- Members of QOC and its subcommittees should not preferentially receive funding from the ACR through the QOC, and members' presence should not influence committee decisions about projects in which they are involved. Therefore:
 - No members are involved with developing a Call for Letters of Interest to which they plan to respond. Members who are interested in responding to Calls for LOI declare this conflict before the call is conceptualized and recuse themselves from all subsequent QOC / subcommittee discussions related to those calls.
 - Members who have been suggested as possible guideline development team members recuse themselves from any discussions related to confirming that project team (or competitors).
 - If members are involved in projects, they are recused from any future QOC or subcommittee discussions related to their projects that involve decision-making and/or problematic situations with the projects. They may participate in informative project update discussions, at the committee's discretion.

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Project-related Disclosure and Management of COI

Disclosures of relationships are obtained from anyone contributing intellectually to an ACR guideline development project, using either the ACR or the journals' disclosure forms, depending on the stage of the project/review. This disclosure happens at various points in the application, development and approval process, both in writing and verbally. See Table 1 below for more detail about who is expected to disclose and when.

Letter of interest phase

People responding to an ACR Call for Letters of Interest must fully disclose their relationships at the time they submit their LOI, using the ACR disclosure form (see Appendix 4). A completed ACR disclosure form must be included for anyone who is proposed to be intellectually involved in the guideline development project. Each form should list all relationships, including recent (i.e., within 1 year before proposal deadline), existing, and planned (i.e., known at the time the form is completed but not yet begun).

When developing a Call for Letters of Interest, the ACR proactively identifies companies and organizations that may be affected by the work. This "affected companies" list includes but is not limited to pharmaceutical, biotechnology, or other companies that manufacture or market products or therapies that might be affected by the ACR's work, or competitors of these companies. Affected companies are ones that are reasonably likely to be positively or negatively affected by care delivered in accordance with the guideline. The list of affected companies is included in the Call for LOI, with a requirement that disclosures related to these entities must be explicitly included in the written disclosures submitted as part of the Letter of Interest. Note that the affected companies list provided by the ACR 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 also explicitly disclose that information.

PIs of guideline development projects are expected to be free of conflicts of interest (COI) relevant to the subject matter of the project for at least one year prior to the LOI deadline, throughout the project

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until publication, and they are expected to remain free of such conflict of interest for at least one year after publication. The literature review leader is held to these same expectations.

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. 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 significantly more than 51% unconflicted participants overall and on each smaller subgroup to allow for unanticipated mid-project personnel shifts (e.g., a participant drops out due to illness or schedule changes).

The conflict of interest thresholds will be based on an evaluation of relationships, primarily with affected companies. Unless their relationship completely excludes them from participation (e.g., industry employment), a person who has any relationship with an affected company is counted as conflicted (toward the allowed threshold) regardless of the type or subject of the relationship. Finally, although intellectual conflicts of interest are important and should be disclosed, they are ubiquitous and, therefore, the ACR does not count someone with intellectual COI as conflicted (toward the allowed threshold) based on the intellectual conflict alone.

The intent of ACR disclosure/COI policies is not to exclude all investigators with potential conflicts from participating in the project, but 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 ACR's 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 related to the specific agents and approaches used to treat the target disease will be explicitly laid out in the final manuscript. This process and information will be considered in the review process. (See disclosure/COI Policy section of ACR QOC policy, Appendix 5).

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If the Guideline Subcommittee seeks input from topic area experts when making decisions about the guideline development group, these experts must disclose their relationships before they are confirmed, and they may not include any individuals employed by or engaged to represent an affected company.

Development phase

Once a group has been named by the ACR to do the development work, the PI and ACR staff share responsibility for ensuring that any changes in the composition of the guideline development group do not adversely affect the balance originally established in the group. If a person drops out of the group mid-project, an evaluation of the effect on overall group balance is done, and an additional participant may be sought, if needed. If a person needs to be added to the group mid-project, the person will be asked to complete an ACR disclosure form, which must be considered and the person's involvement approved *before* officially inviting the person to participate. If approved to participate, the new person's disclosure information is then shared with the rest of the group.

Similarly, the ACR staff and PI share responsibility for monitoring how any mid-project changes to a group members' disclosure/COI might affect the required majority (51%) of development group participants without COI.

At the beginning of the development phase of the project, disclosures are disseminated electronically to everyone in the development group. Individuals review their disclosures every 6 months and update them, if needed; a summary of all participant disclosures is then shared in electronic format with everyone involved in the development effort. Verbal disclosures of changes that are warranted but have not yet been made to written disclosures are provided at the beginning of meetings/calls, before panel deliberations, as necessary. At the beginning of each meeting or call, the project PI or guideline panel chair reminds participants of this requirement.

At a minimum, guideline panel members with COI are recused from voting and drafting text on issues related to their conflicts. Panel member abstentions from voting during guideline development processes are noted in writing so they can be included in the disclosure information that is posted online

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with the final publication. *(NOTE: As of January 2015, this policy has not yet been implemented in ACR guidelines, but it is the intention of the ACR to do so if the logistics can be worked out.)*

Guideline project development group members or ACR representatives may not discuss a guideline's development with employees or representatives of affected companies. In addition, they may not accept unpublished data from affected companies, nor permit affected companies to review guidelines in draft form.

Post-development / Final publication phase

All ACR-approved guidelines must include in the final publication full (not just relevant) disclosures of relationships from authors and anyone who contributed intellectually to the work, plus members of the ACR Guideline Subcommittee, who were responsible for reviewing the paper. Papers must also reference 1) disclosures of the members of the ACR QOC and Board of Directors (at the time the paper was reviewed and approved), which are made publicly available online, in perpetuity; and 2) any abstentions from voting during guideline development processes.

Members of guideline panels are expected to decline offers from affected companies to speak about the guideline on behalf of a company, in any setting, for a period of one year after publication of a guideline. PIs of guideline development projects are expected to remain free of COI for at least one year after publication; the ACR has the same expectation of lit review leaders.

If there are any ACR manuscript reviewers who are not members of the ACR Guideline Subcommittee, the QOC, or the ACR Board, they must submit written disclosures as part of the reviewer selection process, before they are sent the guideline for review. Because non-committee manuscript reviewers are confidential, neither their names nor their disclosures are made publicly available.

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Table 1: Disclosure Requirements for Guideline Development Projects

| | In writing | Verbally |
|---|---|--|
| PI applicant, and all members of the guideline project development group, including systematic review team and guideline panel members | Initially via ACR form included in LOI or via separate communication from ACR (if the person's name was not included in an LOI), then update every 6 months | At start of mtgs/calls, if any update has not been provided in writing |
| Experts/consultants who provide guidance on any aspect of application review, development or final review/approval process | At the point of involvement, then every 6 months, if longer term involvement; via ACR form | At start of mtgs/calls, if any update has not been provided in writing |
| Guideline Panel Members | See above (i.e., initially via ACR form with LOI or via separate communication if the person's name was not included in an LOI), then update every 6 mo.) | Before panel deliberations/voting begins |
| Manuscript authors | At time of manuscript submission to ACR and journal, via journal form | |
| Non-committee manuscript reviewers (ACR) (if any) | As part of ACR reviewer selection process, via ACR form, before they are confirmed and sent the manuscript for review | |
| Manuscript reviewers (journal) | Journal manuscript reviewers are asked to decline an invitation to review if they have conflicts of interest | |
| Staff (methodological/content contributors, not admin. staff) | Initially via ACR form, then update every 6 months | At start of mtgs/calls, if any update has not been in writing |

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Appendices

1. ACR Topic Suggestion Form
2. ACR Generic Call for Letters of Interest Template
3. ACR Guideline Development Process, Deliverables, Timelines
4. ACR Disclosure Form
5. ACR Indirect Cost Policy
6. ACR Quality of Care Policies and Procedures
7. Roles and Responsibilities of ACR Guideline Project Members and ACR Staff/Committee Volunteers
8. ACR Protocol Template
9. Standardized Format for Published ACR Guidelines

ACR Call for Topic Suggestions for Evidence-Based Clinical Practice Guidelines

The ACR maintains current guidelines in the areas of rheumatoid arthritis, osteoarthritis and osteoporosis. Other guidelines are developed, as necessary, based on known gaps in care and developments in the rheumatology field, as resources for such development are available. The ACR will partner with other organizations, as appropriate, in setting priorities in areas of common interest.

*The ACR seeks input from its members and the broader rheumatology community via this Call for Topic Suggestions. Interested parties are invited to submit a completed Topic Suggestion form at any time. Suggestions submitted by **September 15** of each year will be considered by the ACR annually, beginning at the fall ACR Guidelines Subcommittee meeting, for possible funding and project start as early as the following July. If desired, those who submit topic suggestions may inquire about the status of their suggestions by e-mailing quality@rheumatology.org after March 1 of the year following their submission.*

1. Please provide a **short title and the specific objective(s)** for the proposed guideline and an **overview** for a total of not more than 2 pages, with key supporting references.
2. Is the **burden/importance** of the condition/health care intervention large enough to warrant guideline development? Please provide some estimate of the burden (e.g., incidence, prevalence, costs).
3. Is there **uncertainty or controversy** about the relative effectiveness of the available clinical strategies for the condition(s) for which a guideline is proposed? Please provide some examples/assessment of this uncertainty.
4. Is there perceived or documented **variation in practice** in the management of a given condition or use of a particular health care intervention? Please provide some assessment/references related to significant differences in practice patterns.
5. Is there sufficient **scientific evidence** of good quality to allow development of a guideline? Please provide some references, in particular, randomized controlled studies, to support the development of systematic reviews and analysis of the topic.
6. Are there **existing guidelines** on the proposed topic? If a guideline were to be developed, assuming appropriate dissemination, do you believe that it would make a significant **impact** on clinical decision-making/clinical outcomes and/or reduce practice variation?

Thank you for your input into the ACR's guideline development work. Your suggestion is appreciated and will be considered by ACR during the next topic review cycle.

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Call for Letters of Interest from Potential Guideline Development Partners

DEVELOPMENT OF NEW AMERICAN COLLEGE OF RHEUMATOLOGY RECOMMENDATIONS FOR THE PREVENTION AND TREATMENT OF GLUCOCORTICOID-INDUCED OSTEOPOROSIS

Release Date: January 16, 2015

Deadline for Letters of Interest (receipt deadline): May 15, 2015

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

The guidelines will be developed primarily for rheumatologists who care for patients with osteoporosis, but may also be used by primary care providers and others who care for these patients. The guidelines will be developed in accordance with the ACR's standardized approach, which includes use of the [GRADE methodology](#). Overall, the guidelines 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 these guidelines. Letters of interest will be accepted from teams as well as from individuals who are not proposed part of a team. Well-formed teams will be given preference over individuals, but the ACR may 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. The successful letter of interest will:

- 1. Propose 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 care for patients with glucocorticoid-induced osteoporosis. It will include private practitioners as well as academicians and at least one knowledgeable consumer and one patient advocacy group representative. Rheumatology private practitioners and academicians must be included.
- 2. Divide the proposed guideline development group into the following sub-groups:**



- A **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 project plan and timeline that are finalized after the guideline development team is confirmed. Other members of the Core Leadership Team must include the **literature review leader** and the **guideline panel leader**, if the PI is not serving in this role (see below).
 - A **Literature Review Team** of approximately 4-5 people, led by a designated **literature review leader** who is part of the Core Leadership Team. The Literature Review Team will conduct the review of available evidence that will serve as the basis of the recommendations made in the guideline, according to ACR project timeline and schedule for deliverables. NOTE: Because of the PI's prominent role in development of the final guidelines 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 that the ACR may choose to name a literature review team that is separately chosen for this role, depending on the expertise and methodological background deemed necessary for this project. In this case, the lit review team would be integrated into the overall guideline development team.
 - 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.
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. 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 significantly more than 51% unconflicted participants overall and on each smaller subgroup to allow for unanticipated mid-project personnel shifts (e.g., a participant drops out due to illness or schedule changes).
 - **The project PI must not have conflicts of interest related to the subject matter of the guideline.**



- **The literature review and voting panel leaders should also be unconflicted with regard to the subject matter of the guideline.**

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 ACR's 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 RA 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 that will be developed by the ACR once the guideline development team has been confirmed.
- 5. Affirm a commitment to keep all guideline deliberations and materials confidential until publication.** This includes a commitment to NOT participate in other, non-ACR guideline 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 conducted by the ACR's librarian, to help the ACR determine if a guideline update is warranted. See pages 23-25 of the [ACR Guideline Manual](#) for more details about this annual ACR 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 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 has budgeted for and will cover all project expenses directly. 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. The project budget may also include honoraria for members of the literature review team leadership and the voting panel to acknowledge their efforts and time spent on this activity, and possibly other consultants deemed necessary for the successful completion of the project. 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 GUIDELINES

- 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 guidelines will be copyrighted by the ACR. Upon final approval by the ACR, the recommendations will be known as the 2016 American College of Rheumatology Recommendations for the Prevention and Treatment of Glucocorticoid-induced Osteoporosis. The guidelines, including any future updates, will also 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](#). 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 would 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; **applications that do not include a CV/biosketch and a completed disclosure form for all intellectually involved persons will 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 directly 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.

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.

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 (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.

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 May 15, 2015 to:

Practice Guidelines 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. Miller (amiller@rheumatology.org) or Regina Parker (rparker@rheumatology.org).

1. The AGREE Next Steps Consortium. Appraisal of guidelines for research and evaluation II: AGREE II instrument. The AGREE Research Trust; 2009. Available: <http://www.agreetrust.org/new-agree-ii-training-tools/> (accessed 2011 Jun 28).

ACR GUIDELINES DEVELOPMENT PROCESS OUTLINE, INCLUDING TIMELINE

GUIDELINES FOR THE MANAGEMENT OF *(insert topic)* PROJECT PRINCIPAL INVESTIGATOR: *(insert name)*

| TASK | DATE | RESPONSIBLE PARTY | PERSON / PEOPLE ACTUALLY DOING WORK | *SIGNATURE/ INITIALS OF PERSON(S) RESPONSIBLE |
|--|--|---|---|---|
| PHASE 1: PREPARATION/APPLICATION | | | | |
| 1. Complete response to Call for Letters of Interest and submit to ACR | 2 months after LOI deadline | Individuals or teams interested in participating in the project | Individuals or teams interested in participating in the project | -- |
| 2. Identify guideline project development group, including systematic review and guideline panel leader, if the latter is not the project Principal Investigator | | | | |
| 3. Guideline project development group will include those involved in systematic review and those on guideline voting panel <ul style="list-style-type: none"> i. Include clinicians, methodologists, and consumer/patient representative ii. Identify working group (e.g., fellows and staff) | | | | |
| 4. Include completed ACR disclosure forms for all participants | | | | |
| PHASE 2: DEVELOPMENT: Systematic Review | | | | |
| 5. Convene project leadership and systematic review team <ul style="list-style-type: none"> i. Discuss GRADE methodology ii. Develop clinical questions (PICO) iii. Discuss protocol development | Month 1 (of agreed-upon GL development timeline) | Project PI /ACR staff | PI, systematic review leader and systematic review team, and Core Team, including leader of guideline panel if s/he is not the PI | |

* Indicates agreement with steps as outlined, including contracted project timeline

NOTE: After the Call for LOI phase, the ACR will review the LOIs submitted and name a Project Principal Investigator (PI), literature review leader, and the rest of the Core Oversight Team. These people will be invited and confirmed, and then letters of agreement will be signed between the ACR and Core Team members (including this initialed document as an attachment). Finally, the ACR will confirm an ACR Board of Directors liaison and a Quality Measures Liaison to the guideline project development group. At this point, development phase 2 begins.

ACR GUIDELINES DEVELOPMENT PROCESS OUTLINE, INCLUDING TIMELINE

**GUIDELINES FOR THE MANAGEMENT OF *(insert topic)*
PROJECT PRINCIPAL INVESTIGATOR: *(insert name)***

| TASK | DATE | RESPONSIBLE PARTY | PERSON / PEOPLE ACTUALLY DOING WORK | SIGNATURE/ INITIALS OF PERSON(S) RESPONSIBLE |
|---|--|--|---|--|
| 6. Protocol development i. Include title, project objectives, clinical questions (PICO), background information, methods (including criteria for considering studies, identification of studies, data collection and analysis), appendices, authors, contributions of project leaders and participants, and declarations of COI/sources of support | Month 1 (of GL development timeline) | Project PI and systematic review leader | PI, systematic review leader and systematic review team, with input into high level discussions (e.g., project objectives, PICO questions) from leader of guideline panel if s/he is not the PI | ** ACR will approve the protocol |
| 7. Systematic review i. Literature search according to approved protocol; management of references in database; preparation of results for screening ii. Data abstraction, quality assessment, analysis iii. GRADE Evidence Profiles, including Summary of Findings Tables | Months 2-5 (of GL development timeline) | Systematic review leader | Systematic review leader, systematic review team, and ACR staff (literature searching, reference management, etc.) | |
| PHASE 2: DEVELOPMENT: Guideline Recommendations | | | | |
| 8. Assess quality of evidence, draft and discuss strength of recommendations, and include patient/clinician preferences, comments, and clinical notes | Months 6-7 (of GL development timeline) | Guideline panel leader (or PI, if he/she serves as guideline panel leader) | Guideline panel leader and guideline panel | |
| 9. Convene Guidelines Panel for final discussion of evidence, drafted recommendations, and final vote | Month 8 (of GL development timeline) | PI | Guideline panel leader and guideline panel | |
| 10. Finalize formal evidence report and 1 st draft of guideline manuscript | Months 9-10 (of GL development timeline) | Guideline panel leader (or PI if he/she serves as guideline panel leader) | Systematic review leader/team (for evidence report) and PI/panel/authors (for GL manuscript) | |
| 11. 2-4 additional phone/webinar meetings to revise and finalize drafts of guidelines | Month 11 (of GL development) | Project PI | PI/panel/authors | |

ACR GUIDELINES DEVELOPMENT PROCESS OUTLINE, INCLUDING TIMELINE

**GUIDELINES FOR THE MANAGEMENT OF *(insert topic)*
PROJECT PRINCIPAL INVESTIGATOR: *(insert name)***

| TASK | DATE timeline) | RESPONSIBLE PARTY | PERSON / PEOPLE ACTUALLY DOING WORK | SIGNATURE/ INITIALS OF PERSON(S) RESPONSIBLE |
|---|---|--------------------------|--|--|
| 12. Final drafted guidelines to ACR, <i>Arthritis Care & Research and Arthritis and Rheumatology</i> | Month 12 (of GL development timeline) | Project PI | PI/panel/authors | |
| 13. Respond to ACR and <i>Arthritis Care & Research and Arthritis and Rheumatology</i> reviews | Months 13-15 (of GL development timeline) | Project PI | Project PI/authors | |
| 14. Submit disclosures to <i>Arthritis Care & Research and Arthritis and Rheumatology</i> | Month 14 (of GL development timeline) | Project PI | Project PI/ACR staff | |
| 15. ACR and AC&R/A&R approvals finalized | Month 16 (of GL development timeline) | | | |
| 16. Develop Clinician’s Guide/pocket guide/app, approve AC&R/A&R proofs, and work with ACR on publicity plans for guideline | Month 17-18 (of GL development timeline) | Project PI and ACR staff | Project PI and ACR staff | |

*** In order to facilitate uptake and dissemination, the recommendations should be written from the patient (and not the drug) perspective whenever possible. For example, “Treatment naïve RA patients with moderate disease activity and no underlying lung or liver disease can be treated with either MTX, leflunomide...” is a preferred format over “MTX can be considered for patients with (list scenarios).”

Important dates to remember:

Protocol development start date: *(insert date)*

Systematic Review start date: *(insert date)*

Drafted Guidelines start date: *(insert date)*

Drafted guidelines due to ACR, *Arthritis Care & Research and Arthritis and Rheumatology* for final review: *(insert date)*

Anticipated project completion date: *(insert date)*

3. Intellectual Property - Do you currently receive, anticipate receiving, or have a reasonable expectation to receive income from intellectual property sources, including but not limited to copyrights, patents, or licenses?

- YES
- NO

If yes, please describe the nature and source of such intellectual property. _____

4. Research Grants/Contracts - If you are currently listed or have in the past 12 months been listed as PI or other investigator (including clinical studies) please indicate the following:

| Funding Agency | Institution/Group/Title of Study |
|----------------|----------------------------------|
| | |
| | |
| | |
| | |

5. Investments

A. Medical industry - Do you have any medical industry-related investments, including but not limited to stocks, bonds, options, or other form of investment or ownership in companies in the following industries: pharmaceutical, biotechnology, medical education, medical publishing, medical internet, or other healthcare-related endeavors?

| Firm | Type | Current Value |
|------|------|---|
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |

B. Non-Medical industry - Do you have any non-industry-related investments, including but not limited to stocks, bonds, other options or ownership, or contractual relationships with any non-medical companies that might conflict with your duties/position with the ACR? Include any relationship with a company that has or might be considered for a business relationship with ACR.

- YES
- NO

If you answered YES to 5B, please specify below:

Company Name: _____ Investment/Relationship: _____

[The current value need not be disclosed.]

6. Organizational Benefit – Are there any monies obtained or assigned by a university, department, institution, foundation, private enterprise group, or any other entity as a result of your activities (e.g. unrestricted educational grants)?

| Sponsor | Institution | Activity | Current Value |
|---------|-------------|----------|--|
| | | | <input type="checkbox"/> None <input type="checkbox"/> <\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> \$25,001-\$100,000 <input type="checkbox"/> >\$100,000 |
| | | | <input type="checkbox"/> None <input type="checkbox"/> <\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> \$25,001-\$100,000 <input type="checkbox"/> >\$100,000 |
| | | | <input type="checkbox"/> None <input type="checkbox"/> <\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> \$25,001-\$100,000 <input type="checkbox"/> >\$100,000 |
| | | | <input type="checkbox"/> None <input type="checkbox"/> <\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> \$25,001-\$100,000 <input type="checkbox"/> >\$100,000 |
| | | | <input type="checkbox"/> None <input type="checkbox"/> <\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> \$25,001-\$100,000 <input type="checkbox"/> >\$100,000 |

7. Activities with other organizations – Do you currently serve in any official capacity, including any decision-making capacity and/or national or state leadership, with any other professional societies, voluntary health organizations, editorial boards, federal or state agencies, internet companies, or other entities that currently engage in activities that could be considered competitive to the ACR’s interests or activities in areas such as education, advocacy, fundraising, etc.?

| Organization | Position | Value of stipends, honoraria, etc. received in past 12 months |
|--------------|----------|--|
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |

8. Family or Other Relations - In accordance with the ACR’s disclosure policies, relevant financial or other relationships of members of your immediate family should also be disclosed. This includes but is not limited to spouse/domestic partner, parents, siblings, children, and grandchildren. Please list any significant relationships or activities where members of your family may be involved.

| Relation (spouse, child, etc.) | Activity/Position | Current Value |
|--------------------------------|-------------------|--|
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |

| | | |
|--|--|--|
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |
| | | <input type="checkbox"/> None <input type="checkbox"/> <\$5,000 <input type="checkbox"/> \$5,001-\$10,000 <input type="checkbox"/> \$10,001-\$25,000 <input type="checkbox"/> >\$25,000 |

Comments/Explanation - Is there any additional relevant information that you feel should be disclosed or other relationships that you would like to clarify?

CERTIFICATION STATEMENT: The above information is true and complete to the best of my knowledge. I have read and understand the ACR Code of Ethics and other policies relating to my obligations to the American College of Rheumatology. If there are any changes in my circumstances, I will update my Disclosure Statement as promptly as possible.

Name: _____ Signature: _____

Date: _____

Attach additional pages if necessary.

American College of Rheumatology

Indirect Cost Policy and Guidelines

Background

Indirect costs are overhead expenses incurred by the applicant organization as a result of the project, but are not easily identified with the specific project. Generally, indirect costs are defined as administrative or other expenses that are not directly allocable to a particular activity or project; rather they are related to overall general operations and are shared among projects and/or functions. (Indirect costs are sometimes referred to as “overhead costs” and more recently by the government as “facilities and administrative costs.” (F&A)) Examples include executive oversight, accounting, grants management, legal expenses, utilities, technology support, and facility maintenance.

ACR’s position is that, whenever possible, specifically allocable costs of an applicant organization’s project should be requested and justified in the proposal as direct costs, including those for dedicated ongoing project management, facilities, and support (further definitions are provided below). Please note that our categorization differs from the U.S. Office of Management and Budget circular instructions familiar to many U.S. based institutions, in which some of these expenses can only be treated as indirect costs.

While the definition of direct and indirect costs is subject to some interpretation, ACR has established basic definitions for the use of our applicants and prospective applicants, which are included in Attachment A.

Rates

ACR is unable to match the indirect cost rates that the federal government may pay to its applicants and contractors or that the organization itself has determined to be their F&A costs. We recognize this means that our applicants may need to engage in cost-sharing between projects, utilize unrestricted funds, or conduct other fundraising to cover operations costs.

In an effort to simplify our procedures for handling requests for funding of indirect costs, we have developed guidelines to share with all applicants.

To the extent that indirect costs are applicable to an ACR grant, such costs are subject to the following limitations:

- 0% for governmental agencies, private foundations and for-profit organizations
- up to 25% for U.S. universities
- up to 10% for all other non-governmental organizations (NGOs), international organizations and non-U.S. universities

These rates are the *maximum* we allow. If an applicant has an indirect cost rate lower than the maximum provided above, the applicant should *not* increase the funding request to the maximum.

In the full grant proposal, prospective grantees must specifically speak to their indirect cost assumptions. This detailed discussion should be included in the applicant’s budget narrative.

Equipment Exclusion:

When an ACR grant includes purchases of equipment, the applicant cannot recover “depreciation” and other indirect costs related to that equipment because ACR, rather than the applicant, is paying for the equipment. Therefore, we do not apply the indirect cost rates to equipment purchases.

Attachment A

Direct and Indirect Cost Definitions

| Direct Costs | Indirect Costs |
|--|---|
| <p>⇒ Salaries of employees directly attributable to the execution of the project</p> <ul style="list-style-type: none"> ○ Includes Project Management ○ Includes administrative support solely dedicated to the project <p>⇒ Fringe benefits of employees directly attributable to the execution of the project</p> <ul style="list-style-type: none"> ○ Includes Project Management ○ Includes administrative support solely dedicated to the project <p>⇒ Travel for employees directly attributable to the execution of the project</p> <p>⇒ Consultants whose work is directly attributable to the execution of the project</p> <p>⇒ Supplies directly attributable to the execution of the project</p> <p>⇒ Sub-awards directly attributable to the execution of the project</p> <p>⇒ Sub-contracts directly attributable to the execution of the project</p> <p>⇒ Equipment acquired for and directly attributable to the execution of the project</p> <p>⇒ Facilities newly acquired and specifically used for the grant project (excludes existing facilities). Examples include:</p> <ul style="list-style-type: none"> ○ A new field clinic ○ New testing laboratories ○ Project implementation unit office <p>⇒ Utilities for facilities acquired for and directly attributable to the execution of the project</p> <p>⇒ Information technology acquired for and directly attributable to the execution of the project</p> <p>⇒ Internal legal and/or accounting staff and/or external legal counsel or accountants directly attributable to the project</p> | <p>⇒ Facilities not acquired specifically and exclusively for the project (e.g. Foundation, Institute, or University headquarters)</p> <p>⇒ Utilities for facilities not acquired for and not directly attributable to the project</p> <p>⇒ Information technology equipment and support not directly attributable to the project</p> <p>⇒ General administrative support not directly attributable to the project. Examples are as follows:</p> <ul style="list-style-type: none"> ○ Executive administrators ○ General ledger accounting ○ Grants accounting ○ General financial management ○ Internal audit function ○ IT support personnel ○ Facilities support personnel ○ Scientific support functions (not attributable to the project) ○ Environment health and safety personnel ○ Human resources ○ Library & information support ○ Shared procurement resources ○ General logistics support ○ Materiel management ○ Executive management (CEO, COO, CFO, etc.) ○ Other shared resources not directly attributable to the project ○ Institutional legal support ○ Research management costs <p>⇒ Depreciation on equipment</p> <p>⇒ Insurance not directly attributable to a given project</p> |

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Phase 1: Preparation – Priority setting, topic selection, Principal Investigator (PI)/panel selection, project approval and funding

CRITERIA

• **For collaborative projects with EULAR:**

1. ACR and EULAR priority lists are developed or revised annually, informed by:
 - a. Internal organizational discussions
 - b. Periodic surveys of the rheumatology community
 - c. Organizational research agendas, as applicable
2. Every 1-2 years, the ACR and EULAR issue a joint call for proposals, which includes a per project budget estimate, a list of current ACR-EULAR priorities plus an “other” option, to allow for proposals unrelated to the listed priorities, if investigators wish to make the case that the ACR and EULAR should prioritize a particular topic or area that is not already on the joint priority list. The PI (i.e., the project leader or chair) and panel members are generally listed in the proposals received in response to the joint ACR-EULAR call for proposals.
3. The ACR Criteria Subcommittee evaluates all proposals using standard forms with predetermined criteria, and makes recommendations to the Quality of Care Committee (QOC). The QOC reviews each recommended proposal and forwards those that receive QOC approval to the ACR Board of Directors with a recommendation for funding. The Criteria Subcommittee and QOC coordinate the ACR approval process with the EULAR approval process, as needed.
4. Both the ACR Board and the EULAR Executive Committee must come to agreement about jointly funded projects before notification is sent to any applicant re: the status of their proposal. ACR and EULAR determine who will communicate final decisions to which applicants on behalf of both organizations. Approved PIs are expected to work with ACR and EULAR to confirm timelines, milestones, deliverables, and other project parameters in writing before funding can begin.
5. Unless otherwise indicated, approval of the proposal indicates approval of the PI and panel members as outlined in the proposal. If there are concerns about the makeup of a development group, these concerns are relayed to the PI directly, and prompt consideration is a condition of funding. (For example, both ACR and EULAR favor balanced representation of North Americans and Europeans in development groups and their leaders, and EULAR requires that at least 3 European countries are represented in projects it supports.)

• **For projects that are NOT collaborative with EULAR:**

1. The ACR Criteria Subcommittee may, from time to time, recommend projects that are priorities for ACR but not EULAR. In this case, the QOC considers these projects as part of its normal budgetary process and makes an independent decision about recommending them to the ACR Board of Directors for funding approval. If another organizational partner is or should be

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involved, QOC requests Board approval of that relationship at the time of project approval so the relationship can be initiated and its parameters established before the project begins.

2. With rare exception, the ACR uses a Request for Proposal (RFP) process for its criteria projects that are not collaborative with EULAR. Most often, joint ACR-EULAR project proposals that are highly-ranked by ACR but are not selected for joint ACR-EULAR support may be considered for sole ACR support. If warranted by issues of importance, timing, or other extenuating circumstances, however, the ACR may choose to distribute a separate RFP related to a particularly important topic for which no proposals were submitted to the joint call for proposals, or may decide to proceed with a development project without distributing an RFP.
3. PI/panel members are generally listed in the proposals received in response to the RFP.
4. The ACR Criteria Subcommittee evaluates all proposals using standard forms with predetermined criteria, and makes recommendations to QOC. QOC reviews each recommended proposal and forwards those that receive QOC approval to the ACR Board of Directors with a recommendation for funding.
5. Unless otherwise indicated, approval of the proposal indicates approval of the PI and panel members as outlined in the proposal. If there are concerns about the makeup of a development group, these concerns are relayed to the PI directly, and prompt consideration is a condition of funding.

GUIDELINES

1. The Guideline Subcommittee recommends topic(s) to QOC, based partly on periodic needs assessments of the membership, rheumatology community and/or ACR leadership. These needs assessments are considered in the context of Guideline Subcommittee members' knowledge and investigation of discussed topics, as well as known topics of concern in rheumatologic care.
2. The QOC considers the subcommittee-proposed topics as part of its normal budgetary process and makes a decision about recommending them to the ACR Board of Directors for funding approval. If the QOC desires possible involvement of another organization in either the guideline development or approval processes, the QOC requests Board approval of that relationship at the time of project approval so the relationship can be initiated and its parameters established before the project begins.
3. Once a guideline topic has been approved by the ACR Board of Directors, the Guideline Subcommittee develops a Request for Proposals.
4. The RFP is distributed to the ACR membership and posted online.
5. Letters of intent are due one month after the RFP is posted. The purpose of the LOI is to help the ACR plan for the proposal review, not to seek permission to submit a proposal. Applicants do not need ACR approval of their LOI before they submit an application.
6. Applications are due a maximum of 4 months after the RFP is posted.
7. Applications are reviewed by experts and then the ACR Guideline Subcommittee. Experts and subcommittee members evaluate the applications using a standard form with predetermined criteria.
8. The subcommittee then makes a recommendation to the QOC about which applicant should develop the guidelines.
9. The QOC makes a final decision, which is then conveyed to all applicants (i.e., project PIs).

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QUALITY MEASURES

- **Linked to ACR guideline development**

1. It is the ACR's goal to develop quality measures immediately after ACR guideline development, in most cases. This timing conserves resources and ensures that quality measures are as updated as possible. When evaluating and approving a guideline proposal, the QOC considers (often in consultation with the Quality Measures Subcommittee) if the topic warrants quality measure development. Whenever possible, a Quality Measures Subcommittee representative is included in the related ACR guideline development group. This person is responsible for monitoring the guideline development project with the quality measure development process in mind, ensuring that the necessary foundation is laid for future quality measure development, including specification.
2. The budget for this quality measure development is included in the QOC annual budget submitted to the ACR Board for approval, separate from the original funding request for guideline development.

- **Not linked to ACR guideline development**

- The Quality Measures Subcommittee may also recommend to QOC topic(s) for quality measure development outside of the guideline development process noted above. In this case, the QOC will consider these projects as part of its normal budgetary process and make a decision about recommending them to the ACR Board of Directors for funding approval.
- If the QOC intends to involve other organizations in the quality measure development or approval processes, the QOC requests Board approval of that relationship at the time of project approval so the relationship can be initiated and its parameters established before the project begins.
 - After Board approval of the project and its funding, the ACR Quality Measures Subcommittee chooses quality measure development group members based on individuals' topic, clinical and measurement expertise and guideline development experience in the topic area.

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Phase 2: Development

1. ACR-funded criteria, guideline and quality measure development projects

A. Standardized methodology and supporting processes

1. **Criteria** – The ACR requires use of standardized criteria development processes, as described in the paper *Development of Classification and Response Criteria for Rheumatic Diseases*, published by the ACR in June 2006.
2. **Guidelines** – The ACR requires use of a standardized, evidence-based guideline development process; with all new guidelines whose development process begins after 2011, use of GRADE methodology will be required. Project PIs partner with ACR staff, following processes, policies and timelines outlined in the ACR Guideline Manual, which is available online at the ACR web site (www.rheumatology.org).
3. **Quality measures** – The ACR requires use of a standardized, evidence-based development process. Particular attention is paid to the policies and endorsement requirements of national organizations such as the National Quality Forum, the AMA Physician Consortium for Performance Improvement, and the Centers for Medicare and Medicaid Services.

B. ACR resources

The ACR seeks to partner with PIs and development teams to produce high-quality products that meet expectations re: the methodology, timeline, budget and deliverables agreed upon by both the ACR and PIs before projects begin. To facilitate this outcome, the ACR provides the following project support, at levels agreed between PIs and the ACR before the start of each project:

- Project funding
- Content, methodology and process expertise, as needed
- Literature searching, study identification and reference management
- Systematic review assistance, as resources permit
- Administrative assistance with logistical details of projects (e.g., meeting planning, conference call/webinar scheduling, communication assistance, and handling direct payments related to meetings, calls and panel stipends or travel expenses)
- Assistance with disclosure and conflict of interest requirements

C. Accountability

Both the ACR and the project PI will have specific responsibilities for which each will be accountable over the course of the project. PIs of approved projects are expected to work with the ACR to confirm project timelines, milestones, deliverables, and related funding details in writing before the initial funding payment will be made. Subsequent payments will be tied to deliverables, with the final payment being tied to project completion and ACR Board of Directors approval of the final publication.

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2. ACR participation in non-ACR-funded criteria, guideline and quality measure development projects

The ACR considers participation in the development of non-ACR-funded projects on a case-by-case basis. For criteria and quality measure development projects, the ACR periodically names panel members and/or liaisons from either its Criteria Subcommittee or Quality Measures Subcommittee to the development group. For guideline development projects, the ACR is more likely to assist organizers with names of experts in a particular area, but designate no official liaison.

Because the ACR is more likely participate in projects that are developed with the rigor of ACR projects, organizers of non-ACR-funded projects who plan to approach the ACR about ACR involvement should pay particular attention to the standardized methodologies and processes accepted by the ACR, as outlined above. PIs of non-ACR-funded quality measure development projects should review the related details described in the ACR Quality Measures White Paper (Saag KG, Yazdany J, Alexander C, Caplan L, Coblyn J, Desai SP, et al. Defining quality of care in rheumatology: the American College of Rheumatology white paper on quality measurement. *Arthritis Care Res (Hoboken)*. 2011 Jan;63(1):2-9).

PIs of these projects should clearly state their expectations up front and outline any financial obligations the ACR might incur as a result of its involvement. These will be considered as the ACR considers its involvement.

ACR participation does not imply or guarantee ACR approval of the final publication or product of the project. Suggested experts and ACR liaisons cannot provide approval for the ACR as an organization. If ACR approval of the final publication or product is desired, the project PI should review the section on ACR approval below as early as possible in the development process and comply with ACR policies and processes as outlined.

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Phase 3: Approval

ACR funding or participation does not imply or guarantee ACR approval of the final publication or product of the project. To obtain ACR approval, criteria, guidelines and quality measures must be formally reviewed by the College.

The ACR reviews criteria, guidelines and quality measures for approval using standardized processes and templates, against pre-determined review criteria. Manuscripts or other submitted documents are subjected to multiple levels of review by subject area and methodological experts. For manuscripts submitted to ACR journals, the ACR and the journals make independent review and approval decisions, although at certain points the administrative processes overlap for purposes of efficiency. The ACR reassesses its review process, as needed, to promote high quality publications, editorial independence, and timely publication.

The ACR will not, in general, review for approval any paper whose authors do not intend to publish the paper in one of the ACR journals (pending journal approval). Exceptions may be made on a case-by-case basis, as recommended by the QOC and approved by the ACR Board of Directors.

CRITERIA

- **Projects funded by both ACR and EULAR**
 - PIs should share a draft of the near-final paper with the ACR Criteria Subcommittee liaison to the development group and ACR staff before submission for publication or ACR approval. The liaison and staff will examine the paper with organizational policies and high-level project goals in mind and provide any relevant feedback to the PI.
 - Final criteria papers from jointly funded projects are published in both *Arthritis and Rheumatism* and the *Annals of Rheumatic Disease*. For each project, one of these two journals will be designated to oversee the review process on behalf of both journals. Once the authors and ACR Criteria Subcommittee liaison/staff agree that the paper is ready, it is submitted to the appropriate journal with a notation in the cover letter that this is the product of an ACR- and EULAR-funded project and, therefore, ACR and EULAR approval is desired. (PIs who are unsure about which journal will oversee review of their paper should contact ACR staff for direction).
 - Concurrent journal and organizational review processes are followed, with periodic requests for manuscript revisions. Authors are expected to respond in a timely manner to these requests so review and approval processes can be completed as soon as possible.

- **Projects funded by ACR (not EULAR)**
 - PIs should share a draft of the near-final paper with the ACR Criteria Subcommittee liaison to the development group and ACR staff before submission for publication or ACR approval. The liaison and staff will examine the paper with organizational policies and high-level project goals in mind and provide any relevant feedback to the PI.
 - Once the authors and ACR Criteria Subcommittee liaison/staff agree that the paper is ready, it is submitted to *Arthritis Care & Research* with a notation in the cover letter that this is the product of an ACR-funded project and, therefore, ACR approval is desired. If such a paper is

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submitted to *A&R* by the authors, the *A&R* editor will forward the manuscript to *AC&R* for review.

- Concurrent journal and organizational review processes are followed, with periodic requests for manuscript revisions. Authors are expected to respond in a timely manner to these requests so review and approval processes can be completed as soon as possible.

- **Projects not funded by ACR**

Requests for ACR approval of drafted criteria papers whose development did not involve ACR may be made by either 1) submitting the manuscript to *Arthritis Care & Research* for publication, noting that concurrent ACR review for approval is desired; or 2) submitting the manuscript directly to the ACR. Direct submission to ACR is reserved for instances when the paper will not be published in *AC&R*; however, ACR approval of criteria papers that are not published in *AC&R* is rare except related to collaborative publications with EULAR or papers whose target audience is not rheumatologists. Authors who desire ACR consideration but are unsure about their submission options are welcome to contact ACR staff for input.

If the investigators are seeking ACR *and* EULAR approval, but neither organization was involved in the development of the criteria or its funding, the draft criteria paper must be submitted to *Arthritis & Rheumatism* to be considered for ACR approval, and the request for ACR and EULAR approval must be noted in the cover letter for the submission. If such a manuscript is submitted to *Arthritis Care & Research*, the *AC&R* editor will forward the paper to the *A&R* editor for review.

- **Levels of ACR approval**

The ACR will consider approval only for those criteria sets that have undergone statistical and quantitative validation. The methods for validating classification and response criteria sets have been well described and may vary depending on the clinical condition. The ACR Criteria Subcommittee has published the following guidance in this area, which criteria developers are encouraged to review and follow:

Classification and Response Criteria Subcommittee of the American College of Rheumatology Committee on Quality Measures. Development of Classification and Response Criteria for Rheumatic Diseases. Arthritis Care Res 2006; 55: 348-351.

There are two possible levels of ACR approval for criteria sets: provisional and full approval. Provisional approval means that the criteria have been quantitatively validated using patient data, but they have not undergone validation based on an external data set. Full approval signifies that the criteria have been quantitatively validated using patient data and have undergone validation based on an external dataset. The ACR strongly encourages interested groups to involve the Criteria Subcommittee early in the process for methodological advice and to help determine whether criteria sets are ready for ACR approval.

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- **Projects funded by ACR**
 - PIs should share a draft of the near-final paper with the ACR Guideline Subcommittee member and staff liaison to the development group before submission for publication or ACR approval. The subcommittee member/staff liaison will examine the paper with organizational policies and high-level project goals in mind and provide any relevant feedback to the PI.
 - Once this initial review is complete, the draft guideline paper is submitted to *Arthritis Care & Research* with a notation in the cover letter that this is the product of an ACR-funded project and, therefore, ACR approval is desired.
 - Concurrent journal and organizational review processes are followed, with periodic requests for manuscript revisions. Authors are expected to respond in a timely manner to these requests so review and approval processes can be completed as soon as possible.

- **Projects not funded by ACR**

Requests for ACR approval of drafted guideline papers whose development was done without ACR support may be made by either 1) submitting the manuscript to *Arthritis Care & Research* for publication, noting that concurrent ACR review for approval is desired; or 2) submitting the manuscript directly to the ACR. Direct submission to ACR should be reserved for instances when the paper will not be published in *AC&R*; however, ACR approval of guideline papers that are not published in *AC&R* is rare (e.g., papers whose target audience is not rheumatologists).

QUALITY MEASURES

The ACR approves quality measures that it develops as well as those developed by others. More details about how the ACR views quality measure development and approval can be found in the ACR Quality Measures White Paper* and through direct discussions with ACR staff and QOC/Quality Measures Subcommittee leadership. Quality measure developers who are interested in ACR approval of their work are encouraged to contact the ACR as early in the development process as possible, to discuss methodology, process, and options for possible approval.

*Saag KG, Yazdany J, Alexander C, Caplan L, Coblyn J, Desai SP, et al. Defining quality of care in rheumatology: the American College of Rheumatology white paper on quality measurement. *Arthritis Care Res (Hoboken)*. 2011 Jan;63(1):2-9

PRACTICAL MANIFESTATIONS OF ACR APPROVAL

Although some situations may be unique, ACR approval typically means:

- **Criteria – ACR-developed and non-ACR-developed:**
 - ACR name in title of publication
 - ACR journal has right of first refusal for publication

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- Posting on ACR web site
- **Guidelines and Quality Measures**
 - *ACR-developed:*
 - ACR name in title of publication
 - ACR journal has right of first refusal for publication
 - Posting on ACR web site
 - *Non-ACR-developed:* If approval is given, the practical details will be negotiated on a case-by-case basis with the person/organization requesting ACR endorsement.

***APPROVAL OF MANUSCRIPTS SUBMITTED FOR PUBLICATION THAT ARE DEVELOPED
BASED ON WORK/DATA GENERATED AS PART OF A RELATED ACR-FUNDED PROJECT***

The ACR does consider for approval publications that are developed as part of an ACR-funded development group's work, but which are not the main goal of that project. Examples include but are not limited to flare criteria developed as part of a response criteria development project, or a literature review used as the basis for later criteria or guideline development.

Some guidance for these situations:

- Authors should request ACR approval by submitting the paper to AC&R with a notation in the cover letter that ACR approval is desired.
- The regular concurrent ACR and journal review processes will be followed as if the publication were the final one for the project.
- Regardless of the ACR approval decision, authors should acknowledge ACR funding of the work as part of the broader project.
- Publication is not contingent on ACR organizational approval; even if the ACR does not approve, authors may publish the manuscript (pending journal approval).

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Phase 4: Publication

- **Projects funded by both ACR and EULAR**

Final papers from jointly funded ACR and EULAR criteria projects are submitted for simultaneous publication in both *Arthritis and Rheumatism* and the *Annals of Rheumatic Disease*. As described above, established processes exist for concurrent organizational and journal review of these papers.
- **Papers approved by both ACR and EULAR but not funded by either organization**

Authors of projects not funded by either ACR or EULAR may request approval from both organizations. The practical implications of this type of joint approval are considered on a case-by-case basis. However, if reviewed and approved by both organizations, these papers are considered for publication in *A&R* (and possibly also *ARD*, pending discussions with EULAR).
- **ACR-funded projects that do not involve EULAR**

With few exceptions, all other QOC products are submitted for publication in *Arthritis Care & Research*. Rarely, publications may be submitted to more than one journal, related to co-endorsement and relevant audience. This will be dealt with on a case-by-case basis with the input of journal editors. When joint products are published simultaneously in more than one publication, the titles and content of the publications will be uniform. The only exceptions to this will be editorial style differences such as those related to American vs. British spelling and formatting of tables. Each article being published simultaneously in both journals should contain a statement indicating it is also being published in the other journal. Timing of dual publications will be synchronized.
- **Papers approved but not funded by ACR**

If an author seeks ACR (but no EULAR) approval for a final product of a project that was not funded by the ACR, that paper should be submitted to *AC&R* with a statement in the cover letter that ACR review and approval is desired. In this case, the standard concurrent ACR and *AC&R* review processes would be followed. Papers submitted to *A&R* are not eligible for ACR organizational approval unless EULAR approval for the paper is also being sought. If authors are unaware of this policy and submit to *A&R* while requesting ACR (but no EULAR) endorsement, however, they will be allowed to have their submission moved to *AC&R*, if desired.
- **Authorship**

Provided investigators have been selected via a competitive RFP process, authorship will be individual, with contributing authors listed by name in the author line of the publication. If investigators were not selected via competitive RFA, corporate authorship must be used unless an exception is requested and granted by the ACR Board during its approval of the final document.

The ACR expects that the project PI will be first author of the final paper(s) that result from a guideline project (i.e., the final guideline). During the project, the ACR expects the guideline

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PI to do the requisite work to justify the first authorship position (e.g., lead the project and draft the final guideline paper). The PI is responsible for making other authorship decisions (i.e., who is an author and what is the appropriate author order), using the guidance of the International Committee of Medical Journal Editors.

- **Names / Titles of ACR-approved papers**
 - **Placement of ACR name**
 - *Joint ACR and EULAR approved criteria papers* – organizational names are placed at the end of the title (e.g., 2010 Classification Criteria for Rheumatoid Arthritis, an ACR-EULAR Collaborative Initiative)
 - *Only ACR* – ACR name is listed at the beginning of the title (e.g., ACR 2010 GIOP Guidelines)
 - **Options for criteria:**
 - “Provisional” approval – not yet validated in external datasets
 - Full approval – validated in external datasets

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Phase 5: Periodic review / revision

- **Updating criteria sets**

It is anticipated that ACR-approved criteria sets will undergo intermittent updates. This will include provisionally approved criteria sets eventually being validated in external datasets and submitted to the ACR for full approval. In general, the ACR encourages investigators to improve upon previous published work – either their own or that of others – and will consider approval of subsequent sets of criteria of the same type and topic if authors of the new paper provide rationale for why the new criteria set is better than the old one, and why the ACR approval should be given to the new criteria rather than the old. The ACR will not simultaneously have 2 approved criteria sets of the same type in the same topic area; if a new one is approved, the old approval will no longer be valid.

If a particular criteria set is determined to be outdated and no updated version has been submitted to the ACR for approval, the ACR (or ACR and EULAR) might choose to distribute an RFP for a new development project, and fund the work itself.

- **Updating guidelines**

As described in the ACR Guideline Manual, ACR guidelines will be reviewed and updated periodically, as ACR funds are allocated and approved for this work. A completely new guideline development project may be necessary if a guideline is determined to be sufficiently outdated. More details about the methodology and processes the ACR uses to decide if a guideline update is warranted are provided in the ACR Guideline Manual.

- **Updating quality measures**

Periodically, quality measures will be reviewed for possible revision or retirement. At minimum, this review will happen each time a revised or new ACR guideline is completed. If no new ACR guidelines are planned, but the quality measures need revision and other updated guidelines are available, these may be used as the basis for quality measure development, at the ACR's discretion.

Each time a document is reviewed and unchanged, a notation will be placed on the electronic version of the document stating that such review has happened, by whom, and the date.

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Disclosure and Conflicts of Interest*

**Some of the policies outlined in this section were approved by the ACR for the first time in late 2010. New policies will be phased in as quickly as possible but might not be retroactively applied to ongoing projects.*

Activities related to the Committee on Quality of Care and its subcommittees should be free from actual or perceived industry influence. Therefore, the ACR does not utilize external support from commercial entities and insurers/health plans for activities of the QOC or its subcommittees. In addition, QOC does not review quality-related products for ACR approval if industry funding was used to support their development. On a case-by-case basis, support may be considered for dissemination materials or strategies.

Disclosure of relationships and management of potential or real conflicts of interest are important at every level of the QOC's work, from prioritizing topics and selecting projects, through development and ACR approval of final papers.

QOC / SUBCOMMITTEE DISCLOSURE AND MANAGEMENT OF COI

The QOC and its subcommittees are guided by two main principles related to disclosure and management of conflicts of interest. One relates to general discussions and decisions, and the other is more specific to particular projects.

- **Members of QOC and its subcommittees should not influence policy decisions based on their relationships with outside organizations, and members should be aware of each others' relationships.** Therefore:
 - QOC members provide written disclosures once each year and update these disclosures as needed during the year. They also verbally disclose at the start of every face-to-face meeting. The QOC chair receives copies of the written disclosures annually for review.
 - QOC subcommittees also disclose verbally at the start of every meeting.
 - Members recuse themselves from any discussions where a potential COI and/or the appearance of a COI exist.

- **Members of QOC and its subcommittees should not preferentially receive funding from the ACR through the QOC, and members' presence should not influence committee decisions about projects in which they are involved.** Therefore:
 - No members are involved with developing an RFP to which they plan to respond. Members who are interested in responding to RFPs declare this conflict before the RFP is conceptualized and recuse themselves from all subsequent QOC / subcommittee discussions related to those RFPs.
 - Members who are involved in a proposal recuse themselves from any discussions related to their proposal (or competitors), and the entire selection process.
 - If members are involved in proposals that are chosen for funding, they are recused from any future QOC or subcommittee discussions related to their projects that involve decision-making and/or problematic situations with the projects. They may participate in informative project update discussions, at the committee's discretion.

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PROJECT-RELATED DISCLOSURE AND MANAGEMENT OF COI

Disclosures of relationships are obtained from anyone contributing intellectually to an ACR criteria, guideline or quality measure development project, using either the ACR or the journals' disclosure forms. This disclosure happens at various points in the application, development and approval process, both in writing and verbally. 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 directly support the person disclosing, medical and non-medical industry investments, organizational benefit, activities with other organizations, and relevant disclosure of first degree family members). See Table 1 below for more detail about who is expected to disclose and when.

- ***ACR-developed projects***

Application phase

Applicants must fully disclose their relationships at the time of application, using the ACR disclosure form. A completed ACR disclosure form must be included for anyone who will be intellectually involved in the project. Each form should list all relationships, including recent (i.e., within 1 year before proposal deadline), existing, and planned (i.e., known at the time the form is completed but not yet begun). Applicant disclosure information is shared with reviewers at each step of the ACR proposal review process.

Investigators whose primary employment is with a pharmaceutical or biotech company are not eligible to participate in ACR criteria, guideline or quality measure development projects, except in rare instances, at the invitation of the ACR, for specific consultation (e.g., a data verification question within a criteria development project). Individuals whose primary employment is with an insurance company are not eligible to participate in ACR criteria or guideline projects, but they may be invited to participate in ACR quality measure projects, if needed, to meet national quality measure development and endorsement requirements.

When developing an RFP, the ACR proactively identifies companies and organizations that may be affected by the work. This "affected companies" list includes but is not limited to pharmaceutical, biotechnology, or other companies that manufacture or market products or therapies that might be affected by the ACR's work, or competitors of these companies. For guidelines, affected companies are ones that are reasonably likely to be positively or negatively affected by care delivered in accordance with the guideline. The list of affected companies is included in the RFP, with a requirement that disclosures related to these entities must be explicitly included in the written disclosures submitted as part of the proposal. Note that the affected companies list provided by the ACR 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 also explicitly disclose that information along with their other relationships.

PIs of ACR project development projects are expected to be free of conflicts of interest (COI) relevant to the subject matter of the project for at least one year prior to the proposal deadline,

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throughout the project until publication, and they are expected to remain free of such conflict of interest for at least one year after publication.

The majority (at least 51 percent) of the 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 proposal deadline and throughout the project until publication. The plan to manage the conflicts of the others must be documented in the project proposal and approved by the ACR prior to the start of the project, with a goal of minimizing the likelihood of inappropriate influence of such conflicts on criteria/guideline/quality measure development. Specifically, the application must describe the procedures or approaches that will be used to deal with individuals' conflicts that may potentially bias how evidence is chosen, assembled, assessed and synthesized, or might bias recommendations that are based on such evidence. This section will be considered as one element of the methods used and will be reproduced in the final publication, together with a description of the review process for the proposed guidelines.

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. If a person is an employee of an insurance company and is working on a quality measure development group, that person is counted as conflicted (toward the allowed threshold). Finally, although intellectual conflicts of interest are important and should be disclosed, they are ubiquitous and, therefore, the ACR does not count someone with intellectual COI as conflicted (toward the allowed threshold) based on the intellectual conflict alone.

The intent of ACR disclosure/COI policies is not to exclude all investigators with potential conflicts from applying for funding or participating in the proposal, but to manage such conflicts in a prospective, structured and reasonable manner. The description of strategies for managing conflicts related to the specific agents and approaches used to treat the target disease must be explicit. The extent and management strategies for conflicts of interest will be considered in the review process.

ACR proposal reviewers must disclose their relationships before they are confirmed as reviewers, and may not include any individuals employed by or engaged to represent an affected company.

Development phase

Once a group has been chosen to do the development work, the PI is responsible for informing the ACR of any desired changes in the composition of their group. If they wish to add someone to the group after the original proposal has been approved, PIs must send a written request to the ACR along with the proposed participant's disclosure form, for ACR consideration and approval, *before* inviting the person to participate. If approved to participate, the new person's disclosure information is shared with the rest of the group.

The ACR and PI share responsibility for monitoring how any changes to the composition of the development group or a group members' disclosure/COI might affect the required majority (51%) of development group participants without COI.

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At the beginning of the development phase of the project, a summary of participant disclosures is disseminated electronically to everyone in the development group. Individuals review their disclosures every 6 months and update them, if needed; a summary of all participant disclosures is then shared again in electronic format with everyone involved in the development effort. Verbal disclosures of changes that are warranted but have not yet been made to written disclosures are provided at the beginning of meetings/calls, before panel deliberations, as necessary. At the beginning of each meeting or call, the project PI or panel chair reminds participants of this requirement.

At a minimum, development group members with COI are recused from voting and drafting text on issues related to their conflicts. Panel member abstentions from voting during guideline development processes are noted in writing so they can be included in the disclosure information that is posted online with the final publication.

Guideline development panel members or College representatives may not discuss a guideline's development with employees or representatives of affected companies. In addition, they may not accept unpublished data from affected companies, nor permit affected companies to review guidelines in draft form.

There may be instances where industry trial data may be reasonable to use in criteria development. However, the involvement of companies or use of their data must be explicitly documented in the final manuscript, including a clear explanation of a company's role (for example, they provided data but did not have input into analysis), scope/limitations of their involvement, why the authors felt it was necessary to use this data and why no other data was available that could satisfy the same purpose (e.g., available registry data had selection bias that the trial data did not). It should also be clarified in the manuscript that the outcome of the trial(s) (whether drug A was better than B or not) was irrelevant to this project, etc.

- ***Non-ACR-developed papers that are submitted for ACR approval***

Those who request ACR approval of their non-ACR-developed work must fully disclose their relationships to the ACR, in writing, before the ACR will consider reviewing the work. This requirement applies to authors and anyone else who contributed intellectually to the work.

All non-ACR-developed papers submitted to the ACR for approval must include a detailed discussion of how potential conflicts of interest were managed to minimize the likelihood of inappropriate influence of such conflicts on criteria/guideline/quality measure development. Specifically, papers should describe the procedures or approaches that were used to deal with individuals' conflicts that could have potentially biased how evidence was assembled, assessed and synthesized or biased the final document based on such evidence. This section will be considered as one element of the methods used and is expected to be included in the final publication, together with a description of the review process for the proposed project. The intent is not to exclude all investigators with potential conflicts from participating in work the ACR approves, but to manage such conflicts in a prospective, structured and reasonable manner. The description of strategies for managing conflicts of interest related to the specific agents and approaches used to treat the disease(s) addressed in

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the project must be explicit. The extent and management strategies for conflicts of interest will be considered in the review process.

- ***Post-development / Final publication phase***

All ACR-approved criteria, guideline and quality measure papers must include in the final publication full (not just relevant) disclosures of relationships, from authors and anyone who contributed intellectually to the work, plus members of the relevant ACR subcommittee responsible for reviewing the paper. Papers must also reference 1) disclosures of the members of the ACR QOC and Board of Directors (at the time the paper was reviewed and approved), which are made publicly available online, in perpetuity; and 2) any abstentions from voting during guideline development processes.

Members of guideline development panels are expected to decline offers from affected companies to speak about the guideline on behalf of a company, in any setting, for a period of one year after publication of a guideline. PIs of guideline development projects are expected to remain free of COI for at least one year after publication.

Any ACR manuscript reviewers who are not members of the ACR QOC or one of its subcommittees, or the ACR Board, must submit written disclosures as part of the reviewer selection process, before they are sent the final criteria, guideline or quality measures for review. Because non-committee manuscript reviewers are confidential, their disclosures are not made publicly available.

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Table 1: Disclosure Requirements for Criteria, Guideline, and Quality measure Development Projects

| | In writing | Verbally |
|---|---|--|
| Applicants (responders to RFPs) | At time of application, via ACR form | |
| Conveners / developers | Initially via ACR form, then update every 6 months | At start of mtgs/calls, if any update has not been provided in writing |
| Committee members and experts/consultants who provide guidance on any aspect of application review, development or final review/approval process | At the point of involvement, then every 6 months, if longer term involvement; via ACR form | At start of mtgs/calls, if any update has not been provided in writing |
| Task force/voting panel members | See above (i.e., initially via ACR form at application point, then update every 6 months) | At start of mtgs/calls, before panel deliberations begin or voting begins, if update has not been provided and shared in writing |
| Manuscript authors | At time of manuscript submission to ACR and journal, via journal form | |
| Manuscript reviewers (ACR) | As part of ACR reviewer selection process, via ACR form, before they are confirmed and sent the manuscript for review | |
| Manuscript reviewers (journal) | Journal manuscript reviewers are asked to decline an invitation to review if they have conflicts of interest | |
| Staff (methodological/content contributors, not administrative staff) | Initially via ACR form, then update every 6 months | At start of mtgs/calls, if any update has not been provided in writing |

Appendix 7: Roles and Responsibilities in ACR Guideline Development

This document is intended to clarify roles in ACR guideline development and expectations of the ACR.

Principal Investigator (PI)* ^

- is responsible for partnering with the ACR to complete all work associated with the guideline development, according to project timelines, milestones, deliverables, and related funding arrangements that are developed and confirmed with ACR
- is responsible for working with ACR staff to ensure that everyone intellectually involved in the guideline project development group^ submits completed ACR disclosure and any other required ACR forms (e.g., confidentiality), at the beginning of the project and at required intervals thereafter
- if requested, works with the ACR to identify two leaders within the overall guideline project development group - one to lead the systematic review of the evidence, and one to lead the recommendation development group / guideline panel^ (NOTE: the PI may choose to also serve as the leader of the recommendation development group / guideline panel, but the PI may *not* serve as the systematic review leader)*
- is responsible for ensuring that a protocol is developed on time, in conjunction with and approved by the ACR, that includes all required elements, to inform the systematic review (see also the description for the Systematic Review Leader below; although the PI cannot lead the systematic review, the PI must work with the ACR to ensure that the selected leader for this part of the guideline development work is fulfilling his/her project responsibilities)
- works with the ACR to develop a plan for guideline panel members to review the results of the systematic review, via electronic communication, conference calls, and/or face-to-face meeting(s)
- collaborates efficiently and effectively with the Guideline Subcommittee Chair and ACR staff, as needed, throughout the guideline development process and publication, including timely responses to any final manuscript revisions requested by either ACR or journal reviewers
- regularly keeps the ACR Board Liaison updated on activities of the guideline development process and engaged, when appropriate

Appendix 7: Roles and Responsibilities in ACR Guideline Development

- works effectively with the ACR Quality Measures Subcommittee liaison to ensure that considerations related to future ACR quality measure development and specification are being meaningfully incorporated into the guideline development process
- is responsible for ensuring that all guideline development group members meet their responsibilities, and if necessary, asks them to resign and replaces them with others
- ensures that the final guideline covers the project scope noted in the approved protocol that is completed before the evidence review is conducted
- is responsible for working with the entire guideline project development group to determine the final guideline author list, including names and their order (NOTE: ACR policy mandates that the PI will be the first author on individually authored guideline papers that are the product of an open process that includes solicitation for guideline development team members; however, corporate authorship is required if an open process was not used, unless an exception is granted by both the ACR and the journals)

Systematic Review Leader

- is responsible for the protocol development for the systematic review that will serve as the evidence base for the guideline, ensuring that appropriate and relevant clinical questions are framed and translated into PICO questions that can be used as the basis for identifying studies
- assigns responsibilities for the preparation of the systematic review to particular literature review team members, e.g., review of papers chosen based on the abstracts, synthesis and interpretation of data, revision, ensuring peer-review, finalizing systematic review
- is responsible for seeing that the literature review is completed in a rigorous and timely fashion that has been agreed upon by the ACR and the Core Oversight Team, and that it is described accurately in the final guideline publication

Recommendation Development Group / Guideline Panel Leader

- ensures that critical and important outcomes are the basis for the guidelines, and that the guideline development team understands the implications for the evidence tables of listing an outcome as “critical” or “important”
- ensures that GRADE methods are followed to make recommendations

Appendix 7: Roles and Responsibilities in ACR Guideline Development

- leads the recommendation development group work, including deliberations about and voting on the final recommendations, whether by phone/webinar, e-mail or face-to-face meeting(s)

Recommendation Development Group / Guideline Panel Members (including the panel leader)

- are responsible for contributing, as needed, to the systematic review, particularly in determining clinical questions that need to be addressed
- are responsible for contributing fully to decision-making about the final recommendations, including evaluating evidence for recommendations, participating in group discussions by e-mail, phone or in person, and meeting deadlines as determined by the Guideline Panel Leader

ACR Board Liaison

- is ideally someone in the 2nd year of term with the ACR Board of Directors, and is named by the Executive Committee of the Board
- can be a guideline project development group member (including part of the guideline panel), but cannot be the project PI
- is responsible for high-level monitoring of guideline development process
- identifies any issues that would be problematic to the ACR Board (e.g., not fulfilling project objectives)
- assists as necessary with staff and Quality of Care relations with PI and the guideline project development group
- participates in major project meetings/calls (including one face-to-face meeting mid-project)

ACR Quality Measures Subcommittee Liaison

- is a member of the ACR Quality Measures Subcommittee or someone named by the chair(s) of that group
- focuses on how individual guideline recommendations might later be translated into a small number of high-quality, evidence-based quality measures, including detailed specification for implementation in clinical settings

Appendix 7: Roles and Responsibilities in ACR Guideline Development

- participates in major guideline project meetings/calls
- helps reduce redundancy between the ACR guideline development, quality measure development, and e-specification processes

ACR Staff

- provides oversight for and daily management of the project, alongside the PI and the rest of the Core Team
- provides process, policy, methodology and content expertise, pulling in ACR committee members, as needed
- provides literature searching/study identification and management of references database as required by project (i.e., if this is not being done by an outside group)
- provides assistance with systematic literature review, as resources permit
- provides administrative assistance with logistical details of projects (e.g., meeting planning, conference call/webinar scheduling, communication assistance, and handling direct payments related to meetings, calls and panel stipends or travel expenses)
- provides assistance with disclosure and COI requirements
- attends and helps lead all meetings/calls of group

* If the PI is also the leader of the recommendation development group / guideline panel, see additional responsibilities for "Recommendation Development Group / Guideline Panel Leader."

^Definitions:

Guideline Project Development Group: includes anyone intellectually involved in the development of ACR guidelines. Includes, but is not limited to, guideline panel members.

Guideline Panel Members: individuals in a guideline project development group who are usually responsible for analyzing available evidence and voting on the final recommendations.

Principal Investigator or PI: the individual who leads an ACR guideline development project, usually named as the primary applicant on the Letter of Interest submitted in response to an ACR Call for Letters of Interest.

Template for ACR Guideline Project Protocol *

A systematic literature review is used as the basis for development of the recommendations within all ACR guidelines. The systematic review is based on a project protocol that is developed by the project PI, systematic review team leader, and selected project participants (including the systematic review team and the leader of the guideline panel, if the project PI is not also serving in this role), in conjunction with the ACR. In addition to serving as the basis for the literature review, the protocol guides project leaders and participants as they work to accomplish the goals and objectives of the project. The protocol is essential to minimize bias and to ensure that the end product(s) delivered meet the needs of the ACR membership and the original intent of the project. The protocol will address broad specifications for the project, as well as the detailed information related to the systematic review.

The protocol will be submitted to the ACR Guideline Subcommittee for final approval before the systematic review is conducted. In addition, the project protocol will be posted on the ACR web site for public comment. Feedback received will be considered as the systematic review begins. If warranted, the systematic review team, PI and ACR may decide to modify the protocol as a result of this evaluation. Responses received during the public comment period will be posted online with the final guideline manuscript, including each respondent's name, professional affiliation, city/state, and disclosure.

The project protocol must include the following information:

1. **Title:** The title should specify the general topic area of the project.

Example:

Project Protocol for Development of ACR RA Guidelines related to Biologic and Non-biologic DMARDs

2. **Project objectives:** Broad project objectives should be clearly outlined.

Example:

- a. *Not specific enough:* Develop rheumatoid arthritis guidelines
- b. *Preferred:* Develop recommendations for the management of rheumatoid arthritis patients with biologic and non-biologic disease-modifying anti-rheumatic drugs (DMARDs)

3. **Clinical questions:** Articulate each clinical question of interest and state the rationale. "Translate" clinical questions into PICO format, i.e., **P**opulation (condition(s), patients, or problem being addressed); **I**ntervention(s) (e.g., treatment); **C**omparator (alternative intervention for comparison, e.g., standard care); and primary and secondary **O**utcomes (critical and important outcomes).

NOTE: If the ACR is partnering with another organization to do the systematic review, the partner organization's format may be used (e.g., AHRQ's "evidence question" format, which is similar to PICO).

4. **Background Information:** Describe the condition, the intervention(s), how the intervention(s) might work, and why it is important to do the systematic review from a decision-making and research perspective.

5. **Systematic Review Methods:**

Criteria for considering studies for the review (inclusion/exclusion criteria)

Outline what will be included in or excluded from the review:

- Types of studies
- Types of participants
- Types of interventions and comparators
- Main or primary outcomes [patient-centered as much as possible, e.g., pain, functional ability]; important and critical outcomes should be the focus, rather than those driven by the available evidence

Criteria for identification of studies

- Describe search methods for identifying evidence/studies, including as a minimum the electronic search strategy in Medline/PubMed, with a note that the search strategy will be adapted for other databases (e.g., Cochrane)
- Indicate which databases and sources of gray literature and other sources will be included
- Specify time periods that will be covered
- Describe limits, if any (e.g., English articles only)
- Outline management plan for references/abstracts
- Include plan for updating searches prior to publication

Criteria for data collection and analysis

Describe:

- How screening of abstracts and articles will be conducted
- Data extraction strategy and data management methods
- Process for resolving disagreements among researchers about study selection and data abstraction
- Information about assessment of quality
- Plan for assessing reporting biases and heterogeneity
- How missing data will be dealt with
- Process for data synthesis (i.e., GRADE approach to rating with Summary of Findings tables)
- Decisions about quantitative and qualitative synthesis strategies
- Planned analyses of differential treatment effects according to patient subgroups, how an intervention is delivered, or how an outcome is measured

6. **Appendices** – Describe what will be included as appendices to the final guideline publication and the systematic review (e.g., electronic search strategy)

7. **Authors:** If the ACR’s usual Call for Letters of Interest process has been followed, the project PI will be first author on the final guideline publication, and other decisions about authorship will

be made at the discretion of this person. These decisions will ultimately be dependent on the efforts made by individuals throughout the guideline development process, using the ICMJE Uniform requirements for manuscripts as guidance. *For the project protocol*, a tentative list of authors of the final guideline document should be drafted, to be modified later in the project if the list is not commensurate with efforts made by project participants.

8. **Contributions of project leaders and participants:** Describe what each participant is expected to contribute to the project.
9. **Declarations of conflict of interest / sources of support:** Include a clear description of all relationships that have been disclosed by project participants and sources of support for the guideline (e.g., ACR).

*This protocol template draws heavily upon Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org. **and** upon information from IOM (Institute of Medicine). 2011. *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: The National Academies Press. [prepublication copy: uncorrected proofs].

Standardized Format/Content for ACR Clinical Practice Guidelines

Title

- American College of Rheumatology (*insert year of publication*) Guidelines for (*insert topic of guidelines*)

Author list

- Names and order should be determined by the Project PI, guided by authorship requirements of the International Committee of Medical Journal Editors . [Uniform Requirements for Manuscripts (URM)]. The Editors; 2009.] The ACR assumes that the Project PI will be the lead author.

Statement about endorsements from other organizations, if any

- *Example:* “These guidelines have been reviewed and endorsed by (*insert organization name*).”

Author affiliations

- Affiliations should be footnoted to the author list

Structured abstract of a maximum of 250 words* including the following:

- Objective: State the rationale for the guideline.
- Participants: Briefly include details about the makeup of the guideline project development group, including skill sets and/or subspecialties represented (e.g., rheumatologists, primary care physicians, a clinician with expertise in GRADE, etc.).
- Process for making decisions [e.g., voting]
- Evidence: Briefly describe how the evidence base was obtained and what grading system was used to grade the evidence (e.g., “This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence.”).
- Conclusions: If possible, summarize the recommendations or, at minimum, state how many recommendation statements were developed, in what general areas, and in which areas recommendations were not made because of a need for further research.

* Abstracts longer than 250 words will be automatically truncated in PubMed records

Conflict of Interest / Financial Disclosure of Panel Members:

- This section should include a description of how disclosures and COI were dealt with in the guideline project, and should explicitly reference further information available online (e.g., documentation of any recusals during the voting process, disclosures of all ACR manuscript reviewers, etc.)

Introduction

- Description of disease, prevalence, burden of illness, etc.
- Purpose of the guideline
- Target audience

Method of Development of Evidence-based Recommendations

- Briefly describe methodology/processes used, including an explanation of the use of GRADE to evaluate the evidence and determine the recommendations in the guideline.

Standardized Format/Content for ACR Clinical Practice Guidelines

Systematic Literature Review

- Provide information about the systematic review that forms the foundation of the guideline recommendations.
- Include information about the development of key clinical questions (i.e., PICO questions) to inform the development of the systematic review and guidelines.
- If the systematic review has been performed by the systematic review team of the ACR guideline project development group, this likely means that the systematic review is not published. In this case, the evidence report should be posted on the AC&R and ACR websites alongside the final guideline, and referenced in the guideline manuscript.
- If the guideline is based on (or in part) on a systematic review that has been published in a peer-reviewed journal, this should be referenced in the guideline manuscript. If the evidence report was done by AHRQ, the report is usually available on the AHRQ website. A link to the AHRQ report should, therefore, appear in the guideline manuscript and on the AC&R and ACR websites.
- Include a web link to the literature search strategies, which should be posted online alongside the final guideline. On the web page where the search strategies are posted, there should be information about databases searched, exact time periods covered, any limits (e.g., English language), when the search was updated, how many people reviewed abstracts and full-text articles, how disagreements were resolved, inclusion and exclusion criteria, and quality assessment used.
- Provide a web link to the full GRADE evidence profiles/evidence report, which should be posted on the AC&R and ACR websites.

Summary of Recommendations

- Each recommendation statement should be explicitly linked to the full evidence report, which should include the GRADE Evidence Profiles, including Quality Assessment and Summary of Findings tables, and to detailed recommendation tables, which should be made available on the ACR web site.
- The detailed recommendations tables should include the voting results of the Guideline Panel members who voted on the proposed recommendation statement; voting results of Guideline Panel members' rating of the overall quality of the evidence; voting results on the strength of the recommendation (i.e., strong or conditional); underlying values and preferences of members of the guideline panel, if possible; and clinical notes and context to assist with the interpretation and application of the recommendation, as appropriate.

Suggested Directions for Future Research

- This section of the manuscript should be used as an opportunity to influence the research agenda for outcomes with little evidence.

References

Acknowledgments

- List people who had responsibility for each part of the guideline development, with author contributions including:
 - Study concept and design

Standardized Format/Content for ACR Clinical Practice Guidelines

- Acquisition of data
- Analysis and interpretation of data
- Manuscript drafting
- Critical revision of the manuscript for important intellectual content
- Statistical expertise
- Administrative, technical, or material support
- Study supervision

Figures and tables will be included throughout the guideline, as appropriate and as noted in the guideline

The following 3 paragraphs will be included in all ACR guidelines:

1. *(1st page)* The American College of Rheumatology is an independent professional, medical, and scientific society which does not guarantee, warrant, or endorse any commercial product or service.
2. *(1st page)* Guidelines and recommendations developed and/or endorsed by the American College of Rheumatology (ACR) are intended to provide guidance for particular patterns of practice and not to dictate the care of a particular patient. The ACR considers adherence to these guidelines and recommendations to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances. Guidelines and recommendations are intended to promote beneficial or desirable outcomes but cannot guarantee any specific outcome. Guidelines and recommendations developed or endorsed by the ACR are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice. At minimum, ACR guidelines and recommendations will be reviewed every two years for potential revision.
3. *(at end of paper)* Addendum: Therapies that were approved after the original systematic review are not included in these recommendations. *(the statement will be modified, as appropriate, if an update was done to any portion of the review after the original review, e.g., immediately prior to panel voting)*