

**AMERICAN COLLEGE OF RHEUMATOLOGY**  
**Policies and Procedures for Quality of Care Committee Work**  
*Submitted to ACR Quality of Care Committee for approval - February 2008*

Outline

- A. ACR Quality of Care Committee (hereafter listed as QOC) Procedures and Policies to Create and Maintain Quality Performance Measures (Subcommittee on Quality Measures), Diagnostic and Response Criteria (Subcommittee on Diagnostic and Response Criteria), and Practice Guidelines (Subcommittee on Practice Guidelines) for Musculoskeletal and Rheumatic Diseases
- B. Internal Structure of QOC / Explanation of ACR Quality Leadership Council
- C. QOC Procedures and Policies for Collaboration with Other ACR Committees and Outside Organizations
- D. QOC Procedures for Setting Priorities
- E. QOC Publication and Web-based Procedures and Policies
- F. Process for Ongoing Review and Revision of ACR Criteria, Guidelines and Quality Measures
- G. QOC Presence at the ACR Annual Meeting
- H. QOC Disclosure/Conflict of Interest Policies

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**A. ACR Quality of Care Committee (QOC) Procedures and Policies to Create and Maintain Quality Performance Measures (Subcommittee on Quality Measures), Diagnostic and Response Criteria (Subcommittee on Diagnostic and Response Criteria), and Practice Guidelines (Subcommittee on Practice Guidelines) for Musculoskeletal and Rheumatic Diseases**

Experiences of the ACR Committee on Research (COR, formerly Council on Research) and the Subcommittee on Clinical Research in past years revealed a need to refine procedures to better ensure fairness and avoid bias in the development and acceptance process, including the development of a level playing field to pick the PI of a specific project and to give the ACR more than one choice, when possible. Proposals may come to the QOC in a variety of ways. What follows was developed with these issues in mind.

**1. Proposal is sent to the QOC (requesting funding from ACR)<sup>1</sup>**

- a. QOC and the relevant subcommittee evaluate (against pre-determined QOC priorities) the need for the particular project and its relevance to the ACR mission.
- b. If deemed needed and relevant, QOC makes a request to the Board of Directors (BOD) for approval and designation of funds to support an RFP that would support project development. When partnering with other organizations, QOC, in association with other ACR leadership, will decide, in advance, case-by-case, how the ACR “endorsement” will be applied (e.g. which organization’s name appears first, etc).
- c. If the project is approved by the BOD, the QOC prepares and releases the RFP for the project. Applicant(s) will be required to send a letter of intent within 4 weeks of the RFP release. RFPs will be posted at the ACR website and disseminated through other routes. The proposal deadline will be set to allow enough time for competing groups to prepare an application, usually 3-4 months following the RFP release. If there is only one letter of

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intent (i.e. from that group making the original proposal), that group will be offered the option of submitting at an earlier deadline.

- d. The RFP outlines recommended methodological principles and development processes specific to each type of project (i.e. criteria, guidelines, quality indicators) so applicants know what is expected.
- e. The RFP outlines the ACR disclosure/conflict of interest policies noted in H.3.a-c, as well as the publication policies listed in A.6.a-d.
- f. Review process for submitted proposal(s)
  - 1) Methodological and topic expert reviewers without project-related conflicts of interest are selected from outside the relevant ACR subcommittee and QOC.
  - 2) Expert reviewers are provided with criteria on which to base their reviews.  
[NOTE: For projects that have already undergone review within the NIH process, the QOC review will focus upon relevance to the ACR.]
  - 3) Expert reviews address approach/methodology, feasibility, and budget.
  - 4) Subcommittee examines expert reviews of proposals and presents its recommendation to QOC (including level of expert and subcommittee consensus and if there was dissension).
- g. Recommendation considered by QOC
  - 1) approved/not approved (majority vote required for approval)
  - 2) budget defined
  - 3) timeline defined
  - 4) method of oversight established
    - 1. Brief update on semi-annual basis, including progress on specific goals, collaborations with other groups, description of departures from original proposal, and any requested adjustments to budget and timeline.
    - 2. Before a project team enters into any new collaborative funding, the subcommittee and QOC must be notified; the QOC has the right to terminate its support of a specific project based on other collaborative funding relationships.
    - 3. The QOC also reserves the right to withhold further funding if sufficient progress is not being made, timeline is not being met, or original project goals and objectives have been altered.

**2. QOC independently identifies need for specific project<sup>1</sup>**

- a. QOC makes a request to the Board of Directors (BOD) for approval and designation of funds to support an RFP that would support project development. When partnering with other organizations, QOC, in association with other ACR leadership, will decide, in advance, case-by-case, how the ACR “endorsement” will be applied (e.g. which organization’s name appears first, etc).
- b. If the project is approved by the BOD, the QOC prepares and releases the RFP (including letter of intent and application deadline dates) for the project (as in A.1.c.)

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- c. The RFP outlines recommended methodological principles and development processes specific to each type of project (i.e. criteria, guidelines, quality indicators) so applicants know what is expected.
- d. The RFP outlines the ACR disclosure/conflict of interest policies noted in H.3.a-c, as well as the publication policies listed in A.6.a-d.
- e. Review process for submitted proposal(s) by QOC
  - 1) Methodological and topic expert reviewers without project-related conflicts of interest are selected from outside the relevant ACR subcommittee and QOC.
  - 2) Expert reviewers are provided with criteria on which to base their reviews.  
[NOTE: For projects that have already undergone review within the NIH process, the QOC review will focus upon relevance to the ACR.]
  - 3) Expert reviews address approach/methodology, feasibility, and budget.
  - 4) Subcommittee examines expert reviews of proposals and presents its recommendation to QOC (including level of expert and subcommittee consensus and if there was dissension).
- f. Recommendation considered by QOC
  - 1) approved/not approved (majority vote required for approval)
  - 2) budget defined
  - 3) timeline defined
  - 4) method of oversight established (as in A.1.g.4.)

**3. Proposal is sent to the QOC (no funding from ACR requested)**

- a. QOC and the relevant subcommittee evaluate (against pre-determined QOC priorities) the need for the particular project and its relevance to the ACR mission.
- b. If deemed needed and relevant, QOC makes a request to the Board of Directors (BOD) for approval and designation of funds, if necessary, to support an RFP that would support project development. When partnering with other organizations, QOC, in association with other ACR leadership, will decide, in advance, case-by-case, how the ACR “endorsement” will be applied (e.g. which organization’s name appears first, etc).
- c. If the project is approved by the BOD, the QOC prepares and releases the RFP (including letter of intent and application deadline dates) for the project (as in A.1.c.)
- d. The RFP outlines recommended methodological principles and development processes specific to each type of project (i.e. criteria, guidelines, quality indicators) so applicants know what is expected.
- e. The RFP outlines the ACR disclosure/conflict of interest policies noted in H.3.a-c, as well as the publication policies listed in A.6.a-d.
- f. Review process for submitted proposal(s)
  - 1) Methodological and topic expert reviewers without project-related conflicts of interest are selected from outside the relevant ACR subcommittee and QOC.

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- 2) Expert reviewers are provided with criteria on which to base their reviews.  
[NOTE: For projects that have already undergone review within the NIH process, the QOC review will focus upon relevance to the ACR.]
- 3) Expert reviews address approach/methodology, feasibility, and budget.
- 4) Subcommittee examines expert reviews of proposals and presents its recommendation to QOC (including level of expert and subcommittee consensus and if there was dissension).

- g. Recommendation made by QOC (majority vote)
  - 1) approved/not approved (majority vote required for approval)
  - 2) budget defined
  - 3) timeline defined
  - 4) method of oversight established (as in A.1.g.4.)

**4. Request is sent to the QOC requesting ACR endorsement for an already created product.**

- a. QOC and the relevant subcommittee evaluate (against pre-determined QOC priorities) the need for a particular product and its relevance to the ACR mission.
- b. If deemed needed and relevant by the subcommittee , the following review process is followed:
  - 1) Completed ACR disclosure forms are obtained from the requestor for all authors.
  - 2) Methodological and topic expert reviewers without project-related conflicts of interest are selected from outside the relevant ACR subcommittee and QOC.
  - 3) Expert reviewers are provided with criteria on which to base their reviews. At minimum, expert reviews address general approach, methodology and the evidence base provided.
  - 4) Subcommittee examines expert reviews of proposals and presents its recommendation to QOC (including level of expert and subcommittee consensus and if there was dissension).
- c. Recommendation considered by QOC
  - 1) Approved/not approved (majority vote required for approval)
- d. QOC makes request to the Board of Directors (BOD) for approval to provide ACR endorsement. When partnering with other agencies, QOC, in association with other ACR leadership, will decide, in advance, case-by-case, how the ACR “endorsement” will be applied (e.g. which organization’s name appears first, etc).

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*Next steps are the same for all possibilities 1-4 above:*

**5. Procedures for “product” and publication**

- a. The manuscript and technical appendix are submitted to the relevant QOC subcommittee, which screens them and determines if they are appropriate for formal review. If not appropriate, the manuscript is sent back to the lead investigator with reasons given.
- b. If the subcommittee deems the manuscript appropriate for review, it is sent for concurrent review by: 1) expert reviewers selected by the subcommittee (potentially including QOC members, subcommittee members, and/or non-committee experts); and 2) *Arthritis Care and Research* (process per AC&R editor).
- c. These reviews are sent together to the lead investigator, who is responsible for revising the manuscript.
- d. The revised manuscript is submitted to the subcommittee and to *Arthritis Care and Research*, with a cover letter addressing all comments.
- e. The subcommittee provides its final recommendation to the QOC, who votes to approve/not approve.
- f. The approved product is submitted to the BOD for approval. The lead investigator will revise/respond to questions or concerns raised by the BOD.
- g. The BOD-approved manuscript is published in *Arthritis Care and Research*.
- h. After publication, the paper or a summary is posted at the ACR website.
- i. QOC will review the specific product according to the review schedule established by the relevant subcommittee to ensure that it remains current (see section F below for more details).
- j. Manuscripts dealing with clinical practice guidelines will include the disclaimer recommended by the AMA (based on application of practice guidelines in courtrooms as Standards of Care and as weapons in prosecution of medical malpractice cases) affirming that practice guidelines are not a substitute for the experience and judgment of a physician and are developed to enhance the physician’s ability to practice evidence-based medicine.
- k. The lead investigator (PI) takes responsibility for the manuscript development, revisions, and all correspondence.

**6. Policies and procedures for publication of ACR Board-approved criteria or guidelines**

- a. *Arthritis Care and Research* is the official publisher of all QOC products.
- b. When products are sponsored by multiple organizations that may have their own journal (e.g. EULAR and *Annals of the Rheumatic Diseases*), products of the research will be published in their journal as well as in *Arthritis Care and Research*. This will be dealt with on a case-by-case basis with the input of journal editors. When joint products are

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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.

- c. Every effort will be made to synchronize the timing of dual publications.
- d. Provided investigators have been selected via competitive RFA, 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.
- e. Every RFP should note the information included in A.6.a-d.

**7. Specific policies related to ACR approval of classification, response and outcomes criteria**

- a. Although the ACR recognizes that they are a necessary part of the criteria development process, “preliminary” criteria sets – those without substantial statistical and/or quantitative validation – will not be endorsed by the ACR.
- b. The ACR will consider ACR endorsement 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 (Felson DT and Anderson JJ, Methodological and Statistical Approaches to Criteria Development in Rheumatic Diseases, Balliere’s Clinical Rheumatology, 1995;9:253-266). Additionally, outcomes/disease activity core set measures that have been validated using prospective/retrospective patient data will be considered for ACR “provisional” approval.
- c. ACR-endorsed classification and response criteria will be named either “ACR Provisional Criteria” or “ACR Criteria.” Provisional criteria would include criteria sets that have been quantitatively validated using patient data, but have not undergone independent validation based on an external dataset; they would be considered provisional until they are validated using prospectively collected trial data in an external data set. At that point, the criteria would be considered fully approved “ACR Criteria.” Outcome/disease activity core set measures will be designated as “Provisional Core Set” if they have been quantitatively validated using patient data. All ACR-approved criteria are expected to undergo intermittent updates.
- d. The ACR strongly encourages interested groups to involve the Subcommittee on Classification and Response Criteria early in the process for methodological advice and to help determine whether criteria sets are ready for ACR endorsement.

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**B. Internal Structure of QOC / Explanation of ACR Quality Leadership Council**

1. QOC meetings will include QOC members and invited guests. Permanent invited guests (5) will include a representative from the ACR Committee on Research (COR), the ACR Committee on Rheumatologic Care (CORC), the Arthritis Foundation (AF) Public Health Officer, the *AC&R* editor and a EULAR representative. QOC subcommittee chairs will be invited guests if they are not full members of the QOC. Periodically others may be asked to attend meetings to address specific topics under discussion.
2. The QOC subcommittees will include:
  - a. Quality Measures
  - b. Diagnostic/Classification and Outcomes/Response Criteria
  - c. Practice Guidelines
  - d. Drug Safety
3. Outside the QOC, the ACR also has an oversight body that spans several ACR committees, called the ACR Quality Leadership Council (QLC). The QLC, which reports to the ACR Executive Committee, is comprised of the chairs of CORC, QOC, the Government Affairs Committee, the Committee on Training and Workforce Issues, and the PIM Subcommittee, plus an ARHP representative and two at-large members. The at-large members must either be a member of the ACR Board or the ACR Executive Committee.

The QLC's purpose is to serve an internal advisory role to provide high level oversight and direction for QOC. In addition, its charge will be to monitor the external environment and plan a rapid, coordinated ACR response to external situations as warranted. These situations would include discussions with and/or responses to 1) insurance carriers and other payors about pay-for-performance initiatives; 2) government agencies or representatives considering legislation related to quality and/or pay-for-performance; and 3) quality-focused organizations that are considering measures sets and/or other quality-related issues.

**C. QOC Procedures and Policies for Collaboration with Other ACR Committees and Outside Organizations**

1. Liaisons
  - a. The following liaisons from outside groups sit on QOC as invited guests: the *AC&R* editor, an ACR Committee on Rheumatologic Care (CORC) member, the Arthritis Foundation Public Health Officer, an ACR Committee on Research (COR) member, and a representative from EULAR. In addition, the chair of the EULAR Standing Committee on International Clinical Studies including Clinical Trials (ESCISIT) is a member of the Criteria Subcommittee. (See also B.1. above).
  - b. A QOC member is named to sit on the following other committees: the ACR Annual Meeting Planning Committee (AMPC) and the EULAR QOC-equivalent committee. The ACR Criteria Subcommittee chair sits on the EULAR Standing Committee on International Clinical Studies including Clinical Trials (ESCISIT).

2. Collaboration and Communication

The ACR recognizes the need to identify other organizations with which to develop collaborations and harmonize. This includes proactive communications with relevant governmental agencies. Such

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collaborations will be developed by the subcommittees. Collaboration may involve cross-membership on subcommittees and publications in two journals.

**D. QOC Procedures for Setting Priorities**

Subcommittees will annually discuss and set priorities for their work areas and submit these to the QOC for its review and approval. Input from the membership/community will be obtained at least every three years through a public comment mechanism on the ACR web site. The subcommittees and QOC will consider suggestions from the membership/community when setting priorities. QOC-approved priorities in its four focus areas – practice guidelines, criteria, quality indicators/measures and drug safety – will be communicated to the ACR Board of Directors annually.

**E. QOC Publication and Web-based Procedures and Policies**

1. *Arthritis Care and Research* is the designated journal for all QOC products.
2. Certain publications may be submitted to more than one journal, related to co-endorsement and relevant audience.

**F. Process for Ongoing Review and Revision of ACR Quality of Care Committee Products**

1. The approval and publication process will generally be the same for practice guidelines, criteria and quality indicators/measures. Original documents will be published in *Arthritis Care and Research (AC&R)*, and any minor updates will be noted within the web version of the document. If major revisions are needed, then the document must be sent through the QOC and ACR Board for reapproval. Each time a document is reviewed, a note will be placed on the document stating which version it is (by date). Whenever a published document is revised after the original document is published, the entire revised document will be republished. This will facilitate access to the full guideline or criteria set, for example, without referencing multiple papers.
2. Nuances of the review and revision process will be handled slightly differently for practice guidelines, criteria and quality indicators/measures, as follows.
  - a. *Practice Guidelines* – Any group that develops a recommendation on behalf of the College will be asked to review and update that recommendation on a regular basis over a period of 5 years. Near the end of the designated 5 years, the subcommittee will decide whether or not a new RFP is needed to rewrite the recommendation.
  - b. *Quality Indicators* – All quality indicators/measures will be placed on a 5-year timetable for review and revision by the Quality Measures Subcommittee. Every year the Quality Measures Subcommittee will review a subset of them, but will review measures earlier than scheduled if a particular area needs immediate attention.
  - c. *Diagnostic and Response Criteria* – All criteria will be reviewed over a 5-year period, in a staggered fashion. If a major revision of a criteria set is needed, a new RFP will be distributed. Very minor revisions can be done by the subcommittee, requesting assistance from previous authors, if necessary (e.g. removing the name of a drug that is no longer available).

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**G. QOC Presence at the ACR Annual Meeting**

1. QOC session proposals are based on a QOC-approved 3-4 year curriculum.
2. One QOC member is asked to develop the curriculum and submit it to the QOC for approval.
3. The duty of developing the specific session proposal each year rotates between the subcommittees.
4. Each session proposal submitted to the ACR Annual Meeting Planning Committee (AMPC) should provide the context of the curriculum and that this is a multiyear program.
5. As noted in C.1.b., a QOC member is named to sit on AMPC.

**H. QOC Disclosure/Conflict of Interest Policies**

**1. Principle.** Members of QOC or subcommittees should not preferentially receive grants from QOC.

Policy:

- 1a. No members of QOC should be involved with developing an RFP to which they plan to respond. Members who are interested in responding to RFPs will take a temporary leave from QOC and subcommittee when such a possibility arises, remain on this leave until the final decision regarding their proposal by the Board of Directors (BOD) has been made, and, subsequent to the BOD decision, will recuse themselves from any discussion related to their proposal.

**2. Principle.** QOC members must not influence policy decisions based on their relationships with outside organizations.

Policies:

- 2a. All QOC members must disclose all potential conflicts annually and update these statements when appropriate, using the ACR disclosure form.
- 2b. All members must disclose verbally such potential conflicts when engaged in committee business pertaining to these issues.
- 2c. All members must excuse themselves from all business where a potential conflict of interest and/or the appearance of a conflict of interest exists. This will be left to the discretion of the member and/or the QOC chair, who will review member disclosures annually or when changes are made mid-year.

**3. Principle.** Those who request ACR endorsement of their work or who apply for ACR Quality of Care Committee project funding must fully disclose their relationships at the time of application.

Policies:

- 3a. Applicants for ACR RFPs must fully complete ACR disclosure forms before obtaining a grant from the ACR. An Appendix to each project application must include completed ACR Disclosure of Conflict of Interest forms for all investigators and collaborators. This is an essential part of the application.
- 3b. Each project application must also include a detailed discussion of how potential conflicts of interest will be managed to minimize the likelihood of inappropriate influence of such conflicts on criteria/guideline/quality indicator development. Specifically, the application should describe

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the procedures or approaches that will be used to deal with individuals' conflicts that may potentially bias how evidence is assembled, assessed and synthesized or bias the final document 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 project. The intent is not to exclude all investigators with potential conflicts from applying for funding or participating in the project, 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 the project must be explicit. The extent and management strategies for conflicts of interest will be considered in the review process.

3c. These requirements (in 3.a. and 3.b.) will be outlined in all ACR RFPs.

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Footnotes

1. If a QOC or subcommittee member wishes to submit a project, he/she will follow steps summarized in H.1.

2. The rationale for an RFP here is that having support for the work may or may not mean that the applicant is the best for anticipated work, and to formally announce the ACR plan for this particular criteria/guideline/quality indicator set before the selection of PI is made. The applicant does indirectly receive credit for work they have done by way of the advantage they have (over unfunded persons) in already having secured funds.