RISE Registry
Data Request User Guide

This is an overview of submitting a request for analysis of RISE Registry data.

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Table of Contents

Preparing your Data Request

To begin your application, you must first choose the scope of your Data Request. RISE offers two request pathways:

- **For Publication** (academic request): For researchers interested in publishing the results as part of a scientific presentation or manuscript.
    - These requests require full subcommittee review, as explained in step three
    - Preliminary Data Track: This track allows researchers who intend to publish their results for a larger project to request a smaller analysis prior to proceeding with the full project. Approved projects on this track would run in two stages:
        - Conduct a smaller project to gather some preliminary data either to assess feasibility or to enhance an application for funding.
        - If the larger project is feasible/funded, update the project plan as necessary and proceed with the analysis.
- **Other** (non-academic request): For researchers interested in the results for internal reference, use in marketing or advocacy materials, etc.

These requests only require partial subcommittee review, as explained in step three.

After deciding on the scope of the project, the next step is to complete the RISE Disclosure Agreement. For the College to most effectively further its mission and to otherwise maintain its excellent reputation in the medical community and with the public, confidence in the College's integrity must be maintained. The cornerstone of the ACR's Disclosure Policy is information on actual and potential conflicts so that the College can evaluate them to avoid undue influence of potential conflicts.

For this form, prepare the following information:

- Your primary employment
- Other streams of monies you receive
- Information on your investments (both medical and non-medical)
- Information on intellectual property rights claims for this project and previous projects
- Sources of personal income
- Your activity with other organizations
- Your family and other relatives' activities with other organizations
- A list of grant and contracts relevant to this proposal

Step 1. Complete Request Form

Next is the RISE Data Use Request Form. This form requires specific information concerning the project you are proposing. In preparation for this stage, please review this sample application available on the RISE website. We also strongly encourage requestors to reach out to RISE staff to discuss their research interests and how RISE data can help answers their questions.

The application asks you to answer general questions on the proposed study, your history, and other related items. Come prepared to answer the following prompts:

- Project type
- PI contact information
- Project background and significance
- How the results will be used
- Characteristics of patients to include or exclude from the project
- Preference on center involvement in development of scientific materials
- IRB requirements
- How the project is funded
- Project objectives and goals
- Specific variables and data needed
- Information on statistical methodology

Step 2. Administrative Review

After your application is submitted, ACR staff will review the request and conduct an initial assessment of the following:

1. Make an initial determination of whether it is feasible
2. Whether it competes with any other requests that are ongoing or have been submitted in the last 24 months

Staff will share the results of this initial assessment and, if needed, provide the requestor an opportunity to make appropriate adjustments to their project request.

Step 3. Research and Publications Subcommittee Review

After administrative review, the proposal will be scheduled for review by the RISE Research and Publications Subcommittee. Projects intended to result in a scientific publication will be reviewed by the full Subcommittee. Requests that do not involve publishing findings will have a partial Subcommittee review.

The RISE Research and Publications Subcommittee will review requests based on the following criteria:

1. The request is feasible given the data available in RISE,
2. The request and study design follow the relevant guidance provided in the AMA's Code of Medical Ethics,
3. The research topic is not too similar to an ongoing RISE data request or one made within the last 24 months.

Step 4. Notice of Review Results

After the Subcommittee has reviewed the request, ACR staff will contact requestors with the results of the review. Potential results include the following:

- **Rejected**: Reviewers have determined that the requested project cannot be completed using RISE data.

- **Revise and resubmit**: Reviewers have identified some areas of concerns in the request, but the project may still be feasible or can be adjusted to longer be in conflict with another project. The requestor will be asked to address the areas of concern, then the revised request will go through Subcommittee review again.

- **Approved as is**: Reviewers have determined that the project is feasible, follows ethical guidance and not in conflict with other projects. If provided, staff will also share any additional feedback on the project from the reviewers.

Step 5. Data Analytic Center Assignment

Approved projects are assigned to one of the RISE data analytic centers (DACs). Datasets are not shared directly with individual investigators or organizations. Instead, the ACR has contracted with DACs with particular expertise in the analysis of clinical rheumatology data. The ACR, requestor, and assigned center will work collaboratively to refine and conduct the analysis.

During this stage, the ACR and the assigned DAC will use the information in the request submission and any additional feedback from the requestor to create a statement of work (SOW) that outlines the project activities, deliverables, milestones and costs. A standard SOW has two phases:

Phase 1: Development of Research Protocol	Phase 2: Protocol Execution
• Refine project plans, • Build definitions for variables based on available RISE data, • Develop table templates, • Finalize research protocol • As needed, conduct some initial patient counts and basic analyses	• Conduct specific analyses as stated in Phase I • Populate tables • Review results with research team • Adjust protocol as needed • Review final tables • Share and review draft report • Deliver final project report

As needed, the SOW will include additional phases, including optional ones, to conduct further work such as exploratory analyses related to the main project and/or development of materials, such as abstracts or manuscripts. Requestors can decide whether or not to pursue these optional analyses at any point during the project. Should the requestor believe additional analyses would be beneficial to the project, those supplements should be included in the SOW. It is easier for the requestor and DAC to eliminate these analyses rather than amend the SOW to add phases after the project has begun.

Step 6. Conduct Analysis

Once the project SOW has been signed, the requested project can begin. As previously mentioned, the requestor, ACR staff and the DAC work closely together to conduct the requested analysis. Communications and document sharing take place in a project management system managed by the ACR. Requestors will be granted access to and trained on the system prior to project initation. Only ACR staff, the requestor's team and the assigned DAC will have access to the project space. The research team will also participate in regular web conferences to review project updates, provide feedback and discuss next steps.

Step 7. Center Delivers Results

As the deliverables defined in the SOW are completed, the results will be shared with the requestor. The requestor will be given the opportunity to review the deliverables and request updates that fall within the project scope or provide approval of the deliverables in their current form. A project will be considered complete when all deliverables have been shared with and approved by the requestor.

Frequently Asked Questions

1. What data is available?

The RISE registry collects all information entered into the EHR systems of participating providers during the course of routine clinical care. Therefore, the RISE registry contains a wide variety of structured and unstructured data, including diagnosis codes, prescription information, lab results, clinical notes, and more. For more information on data relevant to your research question, contact RISE staff.

2. Can RISE send data for analysis to me directly?

No. Currently, the ACR does not release any RISE datasets to individual investigators or organizations. Instead, it contracts with data analytic centers that have both the experience and technical infrastructure to analyze complex, large electronic health record-based datasets.

3. What does a project cost?

Costs vary significantly depending on the complexity of your proposal. However, RISE staff are happy to discuss your analytic needs and impact on budget.

4. How long does a project take?

Timelines are heavily contingent on project complexity. Requestors should allow for a minimum of at least four months after signing the SOW for a project to be completed.

5. Do I need IRB approval for my project?

The ACR has received an exemption from IRB oversight when using RISE data for research purposes by the Western IRB. However, researchers may be required to have their proposed projects independently approved or exempted by their local IRBs.

6. Can I change the SOW after the project has begun?

Yes, during the project, it is possible to make changes through an amendment to the SOW. However, when feasible, the initial SOW should include all potential additional analyses as optional phases. Eliminating optional phases is more straightforward than adding other project needs.

If you would like to include optional phases in your SOW, be sure to include information on all analyses of interest in your data request form with a note that they should be considered optional.

7. Do I need IRB approval for my project?

The ACR has received an exemption from IRB oversight when using RISE data for research purposes by the Western IRB. However, researchers may be required to have their proposed projects independently approved or exempted by their local IRBs.

8. Is there a case report form for RISE?

No. RISE passively collects all data input into EHR systems as it is entered by the providers. Because of this, there is no list of pre-defined data elements. If you would like more details on the data that is routinely collected, contact RISE staff at RISE@rheumatology.org.

9. Can fellows use RISE data for research?

Yes, for funded projects. However, we require anyone who is still a fellow-in-training, a student, or a resident to have identified a mentor before submitting their data request.