

COVID-19 Global Rheumatology Alliance Policy Document

Internal Project Policy, Version 1.

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Purpose

Internal projects need to be managed to maintain quality, achieve the project goals and not allow the C19-GRA's name to be used in an unauthorised way.

DEFINITIONS

Internal Project: One initiated by a member or members of the C19-GRA, and approved as an internal project with the goal to produce an output from a core activity of the C19-GRA AND be authors by the Alliance, as designated by having the C19-GRA as a separate author. For example, results of the registry, or results of a systematic literature review initiated as a core initial activity of the C19-GRA.

Internal Project Types

Including but not limited to:

- Publications on the registry data
- Methods papers, including describing the design and methodology of internal projects
- Reviews of the literature
- Invited or commissioned pieces

External Project: One initiated either by a member or members of the C19-GRA or an external academic institution, company or group with the goal to produce an output that is not a core activity of the C19-GRA or have the Alliance as a separate author. For example, if an investigator external to the group wanted to see what the characteristics of the cases were in a restricted geographical area or a pharmaceutical company wanted to see the pattern of cases using a particular class of drugs.

Core Activity: A core activity of the C19-GRA is an internal project initiated by a member of the C19-GRA and predominantly utilises the resources and personnel of the C19-GRA to fulfill the mission of the C19-GRA.

PROCESS

Project Initiation

Proposals for internal projects to be officially sanctioned by the C19-GRA should be submitted to the steering committee (SC) for review and approval. The SC will make sure that the proposed project is unique (does not overlap with existing projects) and aligned to the goals of the C19-GRA. Anyone with membership in the C19-GRA can propose an internal project. The proposal should be on an internal project proposal form and should be sent to the rheum.covid@gmail.com email address.

Note: Invited or commissioned pieces do not go through the initiation process as outlined above. They go straight to the Steering Committee for review and approval.

Project Review:

The completed proposal form goes to the chair of SC who requested two members of the SC to review and provide a recommendation to the full SC at the next meeting.

Outcomes of a Proposal:

There can be three possible outcomes:

1. The first is project approval but budget not allocated
2. The second is project approved and budget allocated
3. Project not approved. Projects not approved have one right of appeal to the SC. After that, the project has to be substantially revised to be re-submitted for another set of reviews.

It is recommended that project proposals consider the involvement of patient partners and engage with patient partners during the creation of the project. Once the project has been reviewed and if approved in principle, and where the project does not already have patient involvement, the SC will seek expressions of interest for a patient partner(s) to be part of the project team. The process for this will be for the full SC to task the patient members of the SC with running an open process of recruitment to this position, any patient who is a member of the C19-GRA is eligible to be a patient partner assigned to a project team. The role of the patient partner will be to provide patient input and perspective to the project and would be expected to be included in the author list as long as they comply with the Authorship Policies of the C19-GRA.

In addition, a member of the SC or the Data & Study Committee (DSC) will be assigned to be part of the project team. The role of the SC or DSC member will be to monitor the project and ensure that the aims of the project, as set out in the project proposal are adhered to and the quality of the project continues to be that expected of a C19-GRA project.

Project Termination or De-Endorsement

Should a project fail to be managed in line with the project proposal or in other circumstances that lead the SC to believe the project has a limited chance of success then two actions can be taken, the project can be terminated where the project ceases, or alternately if members of the project team wish to continue the project then they can make an application to the DSC to access data through the external project pathway and this then becomes an external project using C19-GRA data.

Projects will need to provide updates to the SC every 6 months (or at an interval determined by the SC) to make sure that progress is being made. The final output needs to be presented to the SC with outcomes. If the project is abandoned, you must inform the SC.

Post Completion Approval

After the project has been completed it needs to be reviewed and approved by the C19-GRA SC, EULAR representatives and ACR representatives prior to submission for publication.

This policy has been drafted by Philip Robinson, edited by member of the C19-GRA and approved by majority vote of the C19-GRA SC on the 16th of April 2020.