COVID-19 Global Rheumatology Alliance Policy Document

External Project Policy, Version 1.

Current as of 16:00 AEST 10-Apr-2020

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OUTLINE

1. PURPOSE

This document provides a framework to help investigators access analyses or clinical data collected through C19-GRA research and data-gathering exercises (collectively referred to as ‘activities’ in this document). **Projects which access data under this policy are deemed to be external projects.** It is intended to be easy to understand, transparent, and equitable.

2. OVERRIDING PRINCIPLES

Primarily, that knowledge generated from data collected by the COVID-19 Global Rheumatology Alliance (C19-GRA) should be as widely disseminated as possible. This will include a variety of audiences and media including, but not limited to Twitter, journal articles, conference presentations, and press releases. In principle, data should be shared with other researchers, research entities and organisations once sharing agreements are established.

3. DEFINITIONS

DSC Data and Sharing Committee (See Appendix 1)

C19-GRA COVID-19 Global Rheumatology Alliance

SC Steering committee (of the C19-GRA)

Internal Project: [Reproduced here as a reference] This is defined as a project initiated by a member or members of the C19-GRA, and approved as an internal project with the goal of producing an output or examining an output from a core activity of the C19-GRA AND with authorship by the C19-GRA. For example, results of the registry, or results of a systematic literature review initiated as a core initial activity of the C19-GRA.

External Project: This is defined as a project 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. For example, if an investigator external to the C19-GRA 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 drug.

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.

4. SCOPE

This policy governs data collected through C19-GRA activities. This policy does not cover data collected and stored by investigators at their own sites for their own use, with their own funds.

5. TYPES OF EXTERNAL PROJECT REQUESTS

a. Academic & Patient Pathway (APP) Requests

Requests directed down this pathway should be from clinicians or academics wanting to answer clinical or scientific questions with an expectation that the results will be published in a peer reviewed journal.

1) In general, basic inquiries or patient cohort counts in support of a grant submission or research activity can be requested from DSC. Formal DSC review is not required for the C19-GRA to provide this level of information. However, the data request does need to be documented in a data request application (DRA).

2) Request for data to be used for research and publication.

3) Request for a Letter of Support (LOS) from the C19-GRA. LOS guaranteeing access to data can be issued for applications that have been formally approved. Other LOS, for example detailing data that are potentially available for a particular project, can be provided by C19-GRA without formal DSC review but do not represent a commitment that data must be provided.

All requests are to be submitted via a DRA.

b. Pharmaceutical or Commercial Pathway (PCP) Requests

Applications through this pathway will be from pharmaceutical companies or other commercial or for-profit entities who do not wish to publish the data. It is a requirement that the data are not published.

Requests through this pathway will enable summary statistics or aggregate data to be released. It will not enable raw data to be released. If raw data are required, then application through the APP pathway is required.

A completed PCP-specific DRA, which will include what information is required, what the information will be used for, who the information will be shared with and when the information will be destroyed.

All requests are to be submitted via a PCP Specific DRA and will attract a processing fee to be determined by the DSC. This processing fee is to reflect the time and resources associated with fulfilling the request and to support the infrastructure required to fulfill the request. The Finance lead for the SC will be consulted to enable an accurate figure to be charged.

6. PROCESS FOR SUBMITTING APP and PCP REQUESTS

In order to batch and review requests in a timely manner, the DSC will assess applications of DRA on at least a monthly basis. These submission deadlines will be posted on the C19-GRA website.

A data request is to be submitted to the C19-GRA DSC on an APP-DRA or PCP-DRA.

The submission contains two elements:

a. An Application. Principal investigator contact info and proposal details that also includes the data fields being requested. Please ensure that the submission specifically addresses:
    - Study feasibility, including a sample size or power calculation
    - Evidence that the investigator has appropriate resources and expertise to conduct the study proposed
    - Timeline of the study

b. Documentation of local IRB/Ethics committee approval for the study, a waiver for the study, or a statement that IRB approval will be obtained. Data will not be released until the applicant provides confirmation of IRB approval or waiver. If IRB approval is not obtained within six months of the application approval, resubmission will be required.

c. The PI must propose a plan that appropriately recognizes the contributions of others, including those on the C19-GRA side as part of the application. The proposal must adhere to the C19-GRA authorship policy and the ICJME authorship guidelines.

7. PROCESS FOR REVIEWING APP AND PCP REQUESTS

7.1 DSC reviews should be completed within 4 weeks of each review deadline.

7.1.1 DSC requests may need to be reviewed by the ACR Quality of Care Committee

7.2 A request for rapid review of a high priority proposal may be considered by the DSC on a case-by-case basis.

7.3 If duplicate and/or overlapping APP applications are received, the DSC may ask investigators to collaborate. If investigators are unable to collaborate, all APP proposals will be scored by the DSC, with preference going to the best-scoring proposal. The exception to this is that PCP pathway projects

7.4 APP applications will be reviewed and scored based upon the 9-point NIH Peer Review and Scoring Process (http://grants.nih.gov/grants/peer_review_process.htm).

7.5 PCP applications will not be scored, and duplicate requests can be approved.

7.6 In prioritising APP requests DSC will give particular consideration to the following applicants:

7.6.1. Investigators who have contributed to the formation and running of the C19-GRA, or are currently involved in C19-GRA internal projects

7.6.2. Investigators who have contributed to the specific collection to be accessed.

7.6.3. Early investigators (EI). A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award or country equivalent.

7.7 At least four DSC members will review each APP or PCP request by the DCS co-chairs. These members will be selected based on relevant expertise and absence of conflicts. To ensure optimal use of C19-GRA data, the DSC may request clarification or revisions from the submitting PI, or solicit additional outside expertise. If responses are requested from applicants, these are expected to be supplied within 30 days.

7.8 The requestor will be notified by email of the decision of the DSC.

7.9 For requests that are not approved:

7.9.1. The DSC will provide the requestor with the rationale for why the request was denied.

7.9.2. In the event that the requestor disagrees with the decision of the DSC, they may appeal to the C19-GRA Steering Committee.

7.10 If the DSC views a request as lacking scientific merit or of a purely commercial or marketing nature they may decline to approve it.

8. POST ADA REQUEST APPROVAL WORKFLOW PROCESS

8.1. APP Data Requests:

8.1.1. The DSC Administrative Lead notifies the C19-GRA Data Warehouse Administrator (DWA) and shares the proposal with them.

8.1.2. The requestor is responsible for making contact with the DWA to ensure the dataset contains the appropriate fields.

8.1.3 Once the release conditions are met (below), the DWA provides the dataset in the format agreed upon with the requestor.

9. DATA RELEASE CONDITIONS FOR ADA REQUESTS

9.1 Research conducted with C19-GRA data and samples must comply with all applicable laws and ethical principles, as well as C19-GRA and institutional requirements. These include Health Insurance Portability and Accountability Act (HIPAA) regulations and/or country specific equivalents and C19-GRA policies on ethics and conflict of interest. The principal investigator requesting the data is responsible for compliance. (http://sourcebook.od.nih.gov/ethic-conduct/ethical-conduct-toc.htm)

9.2 To facilitate transparency, the name of the PI and the title of approved projects will be posted on the C19-GRA website.

9.3 Data will not be provided until IRB approval or an appropriate waiver is provided to C19-GRA. If IRB approval was required, documentation of continued IRB approval must be submitted annually until the project is completed.

9.4 Data transfer must be accomplished under cover of appropriate Data Use Agreements.

9.5 The PI must propose a plan that appropriately recognizes the contributions of others, including those on the C19-GRA as part of the application which adheres to the ICJME authorship guidelines.

9.6 Progress reports are due annually in April of each year (or at a frequency determined by the DSC with regard to the specific project) until the work is published or concluded. These updates should be titled: “DSC Brief Update” in the email subject line and sent to Admin Lead of C19-GRA and may include abstracts, manuscripts, presentations, or other evidence that the project is on track. The DSC will review these progress reports for adherence to project scope and timeline. If progress is not occurring, then the DSC will arrange a conference call with the PI to discuss how to improve study progress.

9.7 Investigators agree to use the data only for the approved research project. If investigators require more data and/or have changed the study focus/question, a new application or an addendum (flexible format at the discretion of the PI) must be submitted. The purpose of this policy is to protect other approved investigators.

9.8 Investigators are responsible for costs associated with supplying the data. If a complex clinical data set is required, a fee may be charged to offset these costs.

9.9 All resulting publications, including abstracts and manuscripts, must be reviewed by the C19-GRA DSC Committee prior to submission. Publications must credit C19-GRA and other relevant sponsors as determined by the C19-GRA Steering Committee, and for data resulting from the C19-GRA Registry, the C19-GRA Registry Investigators and coordinators. Investigators are responsible for the costs of publication. Failure to adhere to this policy will weigh against the investigator's approval to continue the current project or be approved to commence new projects.

10. POST APP REQUEST APPROVAL WORKFLOW PROCESS

The DSC Administrative Lead notifies the C19-GRA Data Warehouse Administrator (DWA) who provides the details to the data analysis team. If there is cost to the applicants (usually for PCP applicants, usually not for APP applicants) the data analysis team will start work on the project once full funding has been received for the project from the applicant.

11. The C19-GRA Data and Share Committee (DSC)

The DSC is responsible for evaluating requests for C19-GRA data by external researchers or groups, or by C19-GRA members who do not want to conduct the research as a C19-GRA internal project.

The C19-GRA Data and Study Committee (DSC) has two Co-Chairs: the C19-GRA Registry Scientific Director and the Steering Committee Chair.

The DSC reports to the C19-GRA Steering Committee.

Four DSC voting members will be assigned to review each request.

The DSC will be composed of the following voting members (size of committee = 8):

- The C19-GRA Steering Committee Chair (Co-Chair)
- The C19-GRA Registry Scientific Director (Co-Chair)
- Two members of the Steering Committee (Excluding the C19-GRA Chair)
- The C19-GRA Data Warehouse Administrator (DWA) [Non-voting]
- Two non-SC C19-GRA members
- One patient representative

Reviewers are assigned by the co-chairs of the DSC based on their expertise and the scope of the project, eg. a patient focused project would include the patient representative as a reviewer.

If any DSC reviewer is in conflict or otherwise unavailable, an *ad hoc* member will be appointed by the DSC Co-Chairs.

If all members are in conflict, then the SC will review the submission or will appoint suitable replacements.

The DSC will periodically review progress reports which will be provided by the administrative lead.

DSC decisions are taken by simple majority vote among the reviewers. If the vote was not unanimous, the DSC administrative lead will follow-up with the 4th reviewer not present to obtain their vote. If there is a tie vote, the final decision will be made by the C19-GRA Executive Committee.

The DSC Co-Chairs are responsible for determining the review and evaluation criteria for data share requests. These criteria are to be reviewed annually and will be updated as needed.

DSC decisions will be reviewed periodically by the C19-GRA Executive Committee.

This policy has been drafted by Philip Robinson, edited by the entire COVID-19 Global Rheumatology Alliance Steering Committee, and approved by the Steering Committee on the 20th of April 2020.