Arthritis Research Coalition (ARC)

Data and sample access and ownership policy

This document covers the procedures that will be used to gain approval to access the clinical and biomaterial collected as part of this network. It also describes the policy for recognizing the contribution made by contributors to the study.

This is a multicenter study involving the collection of clinical data and biosamples from patients with common rheumatic diseases and is funded by Arthritis Ireland. The study staff will be employed by and based in the Clinical Research Facilities in each Hospital group. The primary aim is to underpin clinical and translational research studies and to aid identification of participants suitable for clinical trials.

A Scientific Steering Committee has been established with the remit of overseeing the activities of the network including the use of the data and samples by applicants, both internal and external, using an approved application process.

The Steering committee will meet 6 monthly however requests for access will be considered using electronic communications to expedite decisions to ensure decisions are made within 1 month of submission.

Data & sample access policy

Biomaterials including DNA, RNA and serum will be collected on all participants. These resources are finite and justification for their use and the amount required will be considered by the steering committee.

Data ownership

All data arising from studies (eg genetic, transcriptomic, proteomic) must be sent to the central database.

Authorship

The authorship list of manuscripts arising will be considered on an individual basis and following general rules of authorship[1]. It may not always be appropriate to list each contributing rheumatologist as a co-author, in such cases the lead authors will be named and a collective 'on behalf of the ARC group' included, with the names of group members listed separately. As a general rule however authorship should be as inclusive as permitted by the relevant scientific journal. The final decision on authorship is made with the Scientific Steering Committee.

1. (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)

Application For Access To Data/Samples From The ARC

NB: A letter approving access to ARC data/samples will only be issued once this application has been submitted to and approved by the Steering Committee.

1. Applicants:

Name	Appointment	Institution	Email

2. Address and telephone number of the institution(s) accommodating the project:

3. Address, telephone number and e-mail of the Principal Applicant Title of project:

4. Summary of the project (250 words max)

Please provide in lay terms, a clear and simple summary of the proposed project. Include details of its aims; methods to be used; sample sizes (if applicable); and evaluation plans. A copy of the full study protocol must also be attached.

7. Proposed starting date: _____ Proposed duration: _____

8. (a) Which information / resource does your project need to access from ARC

	Tick if required	Number of samples requested*
Clinical information		
DNA		
Serum		
RNA		

(b) Are these numbers of samples requested based on a power calculation? (c) Briefly describe your calculations

9. Application to grant bodies to fund your project – please give details (if applicable)

1. Name of organisation/source of potential funding
2. Approximate funds to be requested: €
3. Will this process involve peer review? Y/N

Please note that there may be costs incurred to access the data/samples held by ARC– you may need to include these in your grant application. Please ask for details from the Chair of the ARC Scientific Steering Committee, [contact details below] BEFORE you submit your application for funding.

10. Ethical approval

a. Have you applied for Ethical Approval?

b. Is the outcome known? (Please give details)

11. Application form must be approved by representative from your Institution:

Signature: _____ Name and job title: _____

This application must NOT exceed three sides of A4 paper. Please submit by e-mail plus one original by post (***in single spaced typescript***) to:

Chair, ARC Steering Committee,
E- mail: rheumatology@ucd.ie

- All relevant information must be included within this form and should not exceed these 3 pages.
- **A copy of the full study protocol must also be attached**
- The Steering Committee will respond to your request to access data/samples within 28 days – so please allow enough time when preparing your grant application to funding bodies. Data/samples will not be released until funding and ethical approvals are obtained and a signed Letter of Understanding has been received.

Letter of Understanding:
Applicants wishing to access data/samples from the ARC.

1. A completed application form should be submitted to the Steering Committee. This should include a definition of the amounts and types of samples required and/or details of the clinical data required. Only data relevant to that specific project will be released.
2. Data and samples released are the responsibility of the principle investigator, who must ensure that they are not forwarded to, nor access granted indirectly to, any individual not directly connected with the project.
3. The principle investigator is responsible for submission of an annual report to the ARC Scientific Steering Committee whilst their project is ongoing.
4. A preparation and handling charge may be levied for external applicants wishing to access data and samples. In most cases where funding applications are being made to external bodies it is expected that this will be included in their application. This should be discussed with the chair of the Scientific Steering Committee prior to submission of the application.
5. It should be understood that no proposal which replicates prior or concurrent work will be considered.
6. Projects will be given approval with a time limitation built into it i.e. a date by which the project should have commenced. Access to data and availability of samples can not be guaranteed after this date and a re- submission will have to be made.
7. Samples will not be released until proof of funding (where applicable) and Ethical Approval (in all cases) are provided to the committee.
8. Collaborative, multi-centre projects are welcomed by the Committee.
9. Studies involving external collaborators will be allocated a member of the ARC scientific steering committee who will act in a liaison capacity for the duration of the project.
10. All external collaborators are bound by access and ownership guidelines for ARC (available from ARC study coordinator)
11. All publications derived from studies involving this resource are subject to the ARC Authorship policy. Authorship follows the ARC guidelines (available from ARC study coordinator) and must be approved by the ARC scientific steering committee prior to the submission of any publication.
12. All data derived from studies based on ARC data and samples must be provided to ARC after publication, or one year after the completion of the project, whichever is soonest.

Name of principal investigator (please print): _____

Institution (please print): _____

I have read the guidelines above and agree to abide by them.

Signature of principal investigator: _____

Date: _____