

SPIROMICS C4R Ancillary Studies Policy

1. This policy for review by SPIROMICS of C4R ancillary studies applies only to proposals that would use samples or data already collected as part of C4R and not to those requesting pre-existing SPIROMICS samples. The latter require full committee review of our standard ancillary study request.
2. C4R ancillary studies will not be required to be submitted on the SPIROMICS Ancillary Studies Proposal Form. Rather, the C4R Ancillary Studies Form will be considered acceptable.
3. C4R ancillary studies will be given a special designation, C4R-ASXXX, where X = number indicating order of submission.
4. C4R ancillary proposals to use SPIROMICS data will be reviewed by the Ancillary Studies Committee co-chairs, with full committee review an option only if they have concerns. Any decisions by the co-chairs will be communicated to the Ancillary Studies Committee and the Steering Committee during regularly scheduled calls.
5. Items brought up during review that require responses will be addressed in a memo from the PI and attached to the documentation for the ancillary study.
6. For purposes of review by SPIROMICS, Dr. Graham Barr will be contact PI for C4R ancillary proposals.
7. COI forms will be necessary for C4R ancillary studies to SPIROMICS only if a for-profit company is involved in the proposal.
8. Drs. Graham Barr and Prescott Woodruff will regularly publicize opportunities for SPIROMICS investigators to participate in C4R ancillary studies.
9. During co-chair review, Ancillary Studies Committee co-chairs (currently Drs. Wanda O'Neal and Jeffrey Curtis) will pay particular attention to the potential to involve SPIROMICS investigators (maximum of 4 per C4R policy) on issues related to COPD or lung disease, if none are already involved from C4R working groups.
10. SPIROMICS investigators and participants will be acknowledged in C4R publications in a way that is consistent with other cohorts in C4R.
11. Dr. Graham Barr will assure that C4R data for SPIROMICS participants be returned to SPIROMICS.
12. The SPIROMICS leadership should provide assurance that the GIC can support the ancillary study with available resources. The GIC should be consulted to obtain this assurance. (For example, if biospecimens are required, the ancillary study will need to budget for the expense of pulling the specimens, or if data management requests to handle the ancillary study are extensive, consideration should be given to providing the GIC with additional resources).