

COLON CANCER FAMILY REGISTRY (CCFR) RESOURCE AND GWAS DATA SHARING PLANS

Resource Sharing Plan. The CCFRC will continue to build on its history of sharing data with qualified investigators via three of the NCI-recommended methods: direct sharing of data and biospecimens with qualified investigators, publishing peer reviewed manuscripts, and making aggregate data available via a secure website for investigators. A CCFRC project application process will ensure thorough and timely review of applications for scientific merit and feasibility with regard to data and biospecimen availability. This process will be managed by the CCFRC Consortium Coordinator. Applications approved by the Steering Committee will then be triaged by the CCFRC informatics center at the Australasia site, which will take the lead in organizing data requests. They will work with other sites and the requesting investigator to hone the request and dispatch the data. Data Use Agreements and Data Transfer Agreements (for biospecimens) will be negotiated prior to the dispatch of any data or biospecimens. Individual CCFRC site PIs will determine the level at which they can participate. Guidelines for data sharing are:

- a. Resources of the registry should continue to be made available to qualified internal and external researchers in a fair, transparent, and equitable manner;
- b. Resources belong to the specific PI and each PI will decide whether or not to approve their material being used in each particular study;
- c. If a PI refuses permission, their reason/s must be stated in writing;
- d. If a researcher wishes to appeal a refusal for access, they may initiate the Dispute Resolution Process by taking their concerns to the CEC Project Officer for resolution;
- e. The rules of the Dispute Resolution Process will be developed and written by the SC;
- f. The decision of the Dispute Resolution Process is binding;
- g. The process and the rules under which it operates would be publicly available.
- h. In addition, the informatics team will build a website with de-identified aggregate data, which will be available for interested investigators who wish to make an initial determination about the availability of relevant data. The publishing of scientific manuscripts will continue to be a high priority for CCFRC investigators. They will also participate in annual Investigators Meetings with NCI staff and other CEC investigators to foster communication and data sharing.

GWAS data sharing. We propose to share GWAS data and supporting documentation from this proposed cohort study with the scientific community in a manner that is consistent with NIH policy on sharing data for funded GWAS (NIHGuide NOT-OD-07-088 and <http://grants.nih.gov/grants/gwas/>). Data sharing will recognize any individual center/study informed consent restrictions. For potential external collaborators, data will be compiled as de-identified datasets to safeguard participant confidentiality and produced using relevant software. We will make available a standardized dataset after completion of the stated aims of the study. The specific data to be included will be determined by the Steering Committee of the CCFRC comprising PIs of all six involved sites, and in all instances this will be in compliance with all current NIH guidelines. Should any request for data overlap with ongoing or planned (and clearly documented) analyses by the current team of investigators or wider consortium investigators, data will be made available after a reasonable time has elapsed (defined by NIH guidelines) to allow the original investigators time to publish results