

Chapter 6.2 Policy for Small Data Requests to PCGC

6.1 Scope

Scope: When an investigator asks for limited phenotype data on ≤ 10 patients if data already exists in HeartSmart or ≤ 5 patients if data exists in the medical record. A full ancillary study proposal will be required if re-contact with patients is proposed. This may involve probands that are part of published work and probands that have not yet been published.

6.2 Application process

The investigator will submit via email a short description of their project (short paragraph), the type of information requested, and the number of patients involved in their request. The investigator should still work with one of the PCGC PI's, who can guide them through the process and inform them about what type of data is available.

6.3 Approval process

The ACC will distribute the email to the Ancillary Studies Committee who will approve/disapprove the request. The Ancillary Study Committee will take responsibility for determining (through discussion with investigators at their site) if proposed work on unpublished probands overlaps with ongoing PCGC work. *No Steering Committee (SC) approval will be required.* If approved, the investigator will be notified and must agree to appropriate acknowledgement of PCGC in any possible publications involving PCGC patients/data. If disapproved, the investigator will be notified with an explanation for why it was disapproved.

6.4 Acknowledgement

The PCGC will be appropriately acknowledged in any publication that involves PCGC subject(s). The ACC will provide the investigator with an acknowledgement template statement that includes grant numbers and that can be inserted into publications. Any PCGC collaborators that engage in sufficient activities to warrant authorship will be included as an author on publications that involve PCGC patients. This will be evaluated on a case by case basis and will be determined by the collaborator in discussion with the PCGC investigator.

6.5 Data management

The ACC will keep a log of all applications that come in, the gene/variant being evaluated, and whether the proposal was approved or not. This log should be posted so all PCGC centers can easily access it.