I. Request for Shared Data

The NIH has established requirements for sharing data that are produced from NIH-funded research. The NCI has included these requirements as part of the terms of award for all NCI-funded research of the National Clinical Trial Network (NCTN) groups. All NCTN groups, including NRG Oncology, must have an NCI-approved Data Sharing Plan that includes a formal mechanism for processing requests for shared data. The NRG Oncology Data Sharing Policy is available on the NRG Oncology website. It is important to note that request for data sharing can be made only for data elements (patient characteristics, biomarkers, endpoints, etc.) that have appeared in peer-reviewed publications and data sharing is not applicable for any unpublished data element. Note that this requirement thus precludes requests for data related to secondary endpoints and analyses specified in the protocol but not yet conducted and published.

Under the data sharing requirements, any individual from any country may request an NCTN group to provide for the researcher’s independent use any published data that were the basis for results of findings from NCI-funded research. While there are some limitations controlling the release of proprietary information, for the most part, when data from such a publication are requested the request must be granted. Furthermore, when published data are shared through a data sharing request, there can be no stipulations regarding the need for collaboration of the NCTN group statistician in analyses or the inclusion of any member of the NCTN group as a co-author on any publication.

It is important to note that IRB approval from the recipient’s institution and a signed investigator’s agreement are part of the requirements before any data can be shared. Also, reasonable charges for preparation and provision of data are permitted by the NIH policy and may be applicable.

II. Request for Ancillary Data Analysis

An ancillary data analysis is any analysis other than that which has already been identified as the primary or secondary objectives of an approved NRG Oncology protocol. Requests for ancillary data analysis can be made for any available data that were collected as part of an NRG Oncology study with one limitation; generally, a request will not be considered for a protocol for which the primary endpoint of the study has not yet been reported. Ancillary Analysis Applications are evaluated for the scientific merit of the proposed project, the magnitude of effort that would be involved to accomplish the project, the availability of statistical staff to work on the project, and whether the requestor is an NRG Oncology member. Requests from individuals outside of the NRG Oncology membership are rarely considered.

If a request for ancillary analysis is granted, the resulting project is considered as a collaborative activity between the requestor and NRG Oncology and will include statistical staff and other members of NRG Oncology as appropriate. Ancillary analyses are governed by the NRG Oncology Publication Guidelines and are expected to include co-authors as determined by the Publications Committee for any abstract or publication. The collaboration may involve a situation where all statistical support is provided by NRG Oncology or statistical support is a joint effort, with a lot or a little support provided from an outside
statistician. However, in all cases, an NRG Oncology statistician will be included and will have oversight of the effort.

NRG Oncology’s NCI funding intended for carrying out the primary mission of the NCTN, which is to conduct prospective clinical trials. The scale of the funding reflects current and planned trial conduct. Thus, the NRG Oncology statistical team’s day-to-day effort to perform tasks needed in direct support of the NRG Oncology research effort is already substantially extended. Thus, the availability of statistical support for ancillary analyses is limited and only a restricted number of ancillary data analyses can be considered. Processes have been established for submitting a request for ancillary data analysis, for the review of each request, and if approved, the priority ranking for initiation effort on each request. Priority will be given to research which has the potential to have an impact on future NRG research. The NRG Oncology Ancillary Projects Policy and Application is available on the group’s website.

III. Contrasts between the Two Types of Requests

There are four general points of contrasts between these types of requests:

1. Requests for data sharing can be made by any individual, including those who are not NRG Oncology members. Requests for ancillary data analysis can be made by any member of NRG Oncology.

2. Requests for data sharing involve only data elements that have been published, while requests for ancillary data analysis can involve a mixture of data, some of which may or may not have been published.

3. Requests for data sharing do not involve analytical support from NRG Oncology, while requests for ancillary data analysis most typically require analytical support from the NRG Oncology (in some cases requestors may have collaborators who can perform the analysis). However, both types of requests require statistics and data management effort and time, and must be prioritized accordingly with other activities.

4. Requests for data sharing do not involve collaboration or co-authorship by NRG Oncology members, while requests for ancillary analysis do require collaboration and co-authorship by NRG Oncology. These publications are subject to adherence to the NRG Oncology Publications Policy and are considered NRG Oncology Publications.

Questions concerning the Data Sharing and Ancillary Projects Policies can be sent to APC@nrgoncology.org.