NRG ONCOLOGY

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NRG Oncology Ancillary Projects Policy

Version 3: July 9, 2026

PURPOSE

Ancillary Projects and data sharing projects, which are research efforts using data elements already collected in the NRG database that are not part of a protocol-specified analysis, are a high priority of NRG Oncology (NRG). These research projects can provide useful hypothesis-generating information of value to NRG and to society. NRG members, as well as qualified non-members with a member sponsor, are encouraged to apply for opportunities to collaborate with NRG Oncology on scientifically exciting ideas. The Ancillary Projects Committee will facilitate this application and review process, and the general principles of this process are detailed below.

NRG ONCOLOGY ANCILLARY PROJECTS POLICY

1. NRG Oncology is a National Cancer Institute (NCI) funded entity and follows NCI policies and guidelines applicable to sharing data from NCI supported studies. In addition to and separate from Data-Sharing Projects, NRG Oncology has additional policies – detailed below – that govern requests for data and data analyses that are not pre-specified in an NRG protocol document. These analyses are referred to by NRG as 'Ancillary Projects'.
2. Ancillary Projects generally do not begin until the primary endpoint of the relevant study(ies) has been reported and published. In most cases, requests for analyses prior to the primary endpoint reporting will be administratively rejected and applicants will be asked to re-apply in the future. There are occasional exceptions, for example studies in which the primary endpoint may take many years to mature (e.g. early-stage prostate and breast cancer trials). These exceptional requests usually require NRG Oncology Data Monitoring Committee and NCI approval.
3. Ancillary Project requests refer to the use of data elements that have already been collected but are not part of a protocol-specified analysis. Requests for new/additional data not currently in the NRG Oncology database will, in general, be administratively rejected as infeasible.
    a. Proposals to use ***scans of already digitized pathology slides*** are to be submitted as an Ancillary Project request and will be reviewed by the Ancillary Project Committee
    b. Proposals to ***analyze biospecimen material, or digitize pathology slides*** are not part of the NRG Oncology Ancillary Projects process and must be approved by NCI. Information can be found on the Biospecimen Access page on the NRG Oncology website (https://www.nrgoncology.org/clinical-trials/clinical-trial-resources/biospecimens-access/).
    c. Proposals for NRG Oncology data collected in other repositories (i.e., IROC for DICOM data) may require special collaborative agreements in addition to Ancillary Project Committee approval.
4. Ancillary Projects requesting data from secondary and/or exploratory protocol-specified endpoints generally do not begin until the respective endpoint(s) have been reported and published. It is NRG policy that protocol-defined endpoint data cannot be transferred or shared outside of the Statistics and Data Management Center (SDMC) until the corresponding endpoint has been reported and published. For example, protocol-specified quality of life data/endpoints must be reported and published before that data can be shared and/or analyzed as part of an Ancillary Project.
5. NRG Oncology investigators requiring analysis of NRG trial data to aid in the design of a new protocol concept/amendment or to respond to a regulatory authority will work directly with the

responsible committee chair and statistician. An application and review by the Ancillary Projects Committee is not required. Likewise, with notification to NRG Headquarters, the responsible committee chair and statistician may elect to work directly with external organizations that need limited information for trial design.

6. Applications for projects that have already undergone peer review via another NRG Oncology program/process, such as the NCI Community Oncology Research Program (NCORP) pilot grant process, will undergo an expedited review that will be agreed upon by the Ancillary Projects Committee Chair and the applicable NRG Oncology peer-review process team.
7. Principal Investigators with an approved Ancillary Project may not submit another Ancillary Project application until the findings of the ongoing project have been presented at a major scientific meeting or submitted for publication through the NRG Publications Committee guidelines.
8. Ancillary analysis requests will be submitted to the Committee using the Ancillary Project Application Form available from the NRG Oncology website. Applications undergo an initial review for feasibility by NRG headquarters staff and the appropriate disease site statistician(s). The application is then routed to the appropriate NRG disease site or NCORP committee leadership for awareness (for non-feasible applications) and scientific interest (for feasible applications). It is not unusual for multiple applicants to submit very similar, or even duplicative, applications for ancillary analyses. The Committee will adjudicate these situations. To minimize to chance of submitting a duplicative application, potential Ancillary Project investigators are expected to consult the database of approved NRG Oncology ancillary analysis projects available on the NRG Oncology website.
9. If the Ancillary Project is found to be potentially feasible and not duplicative of a current project, it undergoes formal peer review. The Committee considers the application in whole including disease site or NCORP committee chair feedback, statistical review, and a peer review assessment and provides the investigator(s) with a final decision regarding approval or disapproval.
10. The work involved in an approved Ancillary Project request is considerable and is not funded under NRG Oncology's NCI grants. ***It is expected that investigators requesting approval of an Ancillary Project will provide a source of funding and/or resources upon acceptance of their proposal***. The amount of funding required for a project depends on many factors, including the complexity of the project, and time and effort required for data set assembly and/or analyses. The Committee will work closely with the statisticians and administrative staff to determine a fair and equitable budget for each specific project that is submitted and will provide this budget to the investigator(s) for review and acceptance prior to initiation of the Ancillary Project. The Ancillary Project investigators will also agree to a timeline for meeting the payment requirements. If payment is not received in the agreed time period, approval for the project may be withdrawn. Exceptions to the funding requirement may be granted for NCORP pilot project awardees, NRG early career mentored fellows, and for NRG Health Care Access Fellows.
11. Study datasets vary significantly from trial to trial, such that combining data from different studies typically requires significant data preparation to create a unified data set for Ancillary Project analysis. The NRG SDMC has limited resources and thus large, complex projects (e.g., projects involving 4 or more studies, projects using derived variables, etc.) should be discussed with an SDMC statistician prior to submitting an application even if an outside statistician will be used for the analysis so that feasibility concerns can be addressed
12. Requests to amend a previously approved ancillary project application are reviewed by the Committee chair, vice chair, and statistician with input from internal and external reviewers as appropriate. The chairs may administratively approve an amendment request or forward it to the full Committee for final determination.

13. A benefit of NRG Oncology membership includes access to Ancillary Project collaboration. However, NRG also recognizes the potential for important scientific concepts that arise outside of NRG member organizations. In this event, we encourage the investigator(s) to seek an NRG member to support the value of the project as a sponsor and assist with knowledge of NRG, its studies, and processes. The sponsor may act as co-PI, co-investigator, or statistician.
14. Applicants are encouraged to visit the NRG Oncology website for information regarding the application process, a list of previously reviewed projects, NRG Oncology's Data Sharing Policy, and additional information regarding the sharing of the various types of data and materials (e.g., biospecimens or digitized images) from NRG Oncology's NCI funded trials.

Approved by NRG Oncology Group Chairs as of July 8, 2026.

Signed by:
Sharon Hartson Stine
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Sharon Hartson Stine
Executive Director

7/9/2026
Date

Version	Revision Description	Author	Version Date	Effective Date
1	New Policy	Sharon Hartson Stine Joseph Costantino	23Sep2014	23Sep2014
2	Minor editorial changes	Sharon Hartson Stine	02Oct2015	02Oct2015
3	Periodic review, clarifications and additional requirements for applicant.	Sharon Hartson Stine	09Jul2026	13Jul2026