I. Purpose

To outline the general policies for sharing data from National Cancer Institute (NCI) funded trials conducted by NRG Oncology for an investigator’s independent use without involvement of NRG Oncology support of any type. Sharing data from trials that have been or will be deposited into the NCTN/NCORP Data Archive fall outside of this policy as those requests are made to and handled by the NCI. Information on available data in the NCTN/NCORP Data Archive can be found on the NIH website: https://nctn-data-archive.nci.nih.gov/about-us. The procedures outlined in this policy do not apply to requests from the NCI or the Food and Drug Administration (FDA). Those requests are handled administratively and as expeditiously as possible. This policy only covers requests for existing data, not requests for use of tissue or for the collection of additional data.

II. Scope

This policy applies to NRG Oncology Operations Center and Statistics and Data Management Center (SDMC) staff, NRG Oncology members, and external researchers.

III. Procedures

A. Request Procedure

An investigator who would like to conduct an analysis of anonymized clinical data from a published NRG Oncology study funded by the NCI must make a formal request to the NRG Oncology for the data identifying the nature of the intended study for which the data will be used. Requests for clinical data from a trial(s) that will be or has been deposited into the NCTN/NCORP Data Archive must be made to the NCTN/NCORP Data Archive: https://nctn-data-archive.nci.nih.gov.

1. Applicants must submit a Data Request Application Form available on the NRG Oncology website to the Data Sharing Requests Review Coordinator (APC@nrgoncology.org) at the NRG Oncology Operations Center. The documents listed below must be included with the request.
   a. A copy of the investigator’s CV or a copy of the investigator’s biosketch in the NIH format.
   b. The NRG Oncology Data Sharing Application Form that:
      i. identifies the specific NRG Oncology trial(s) and the corresponding publications from which the requested data would come;
      ii. describes the goals and objectives of the investigator’s proposed study and how it will be conducted; and
      iii. summarizes the planned methods for statistical analysis.
   c. An original Investigator Responsibilities Agreement Form for the proposed study signed by the investigator (see Appendix A at the end of this document).
   d. Documentation that the Institutional Review Board (IRB) from the investigator’s institution has approved the investigator’s proposed study.
   e. Written attestation from the investigator that she/he has undergone appropriate Human Subjects Protection training and the date that this training was completed.

2. The NRG Oncology Data Sharing Review Panel will review the request and the proposed study...
for feasibility, and the Data Sharing Requests Review Coordinator will notify the investigator in writing of the decision regarding the approval or disapproval of the data request. If the request is denied, a brief explanation of the reason for denial will be provided to the requesting investigator. A denied request can be appealed through the process described in Section D.

B. Regulatory Considerations

1. It should be noted that requests for data from NRG Oncology studies will only be considered for published data that is outside of the scope of the NCTN Data Archive. Release of data collected in a clinical trial conducted under a binding collaborative agreement between the NCI Cancer Therapy Evaluation Program (CTEP) and a pharmaceutical/biotechnology company must be in compliance with the terms of the binding collaborative agreement and must be approved by CTEP. If the study from which data are being requested involves an agent undergoing FDA review for approval, the release of data will not be considered until the FDA review is completed. Release of the data is also subject to the terms of any contracts between NRG Oncology Foundation, Inc. and/or one of its Member Groups and commercial entities which may govern the proprietary nature of the data. In addition, all release of data are subject to the restrictions stated in Section C and in the case where the study population is small, the release of data may be constrained by the ability to de-identify data.

It is anticipated that individual-level de-identified datasets that would be sufficient to reproduce results provided in a publication (i.e., published manuscript) will be available to investigators no sooner than 6 months after publication of the manuscript.

2. All research use of clinical data is subject to applicable Office of Human Research Protections (OHRP) regulations, Institutional Review Boards regulations and to applicable regulations of the Health Insurance Portability and Accountability Act (HIPAA). Thus, all data files provided to an investigator are stripped of all identifying or potentially identifying patient information. Further guidance is provided in the OHRP document “Guidance on Research Involving Coded Private Information or Biological Specimens” and at the NIH HIPAA Privacy Rule Information for Researchers site. (See Section IV, References.)

C. Data Release Conditions

1. In releasing data to an investigator, NRG Oncology makes no representations and extends no warranties of any kind, either expressed or implied. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the data will not infringe any patent, copyright, trademark, or other proprietary rights. No indemnification for any loss, claim, damage, or liability will be intended or provided.

2. A signed Investigator Responsibilities Agreement is required before data for an approved request will be provided to the requesting investigator.

3. Investigators must agree to use the data only for the approved research project. If the investigator later wishes to use the data in a new project, a new proposal must be submitted, reviewed and approved.

4. Investigators must agree to keep all of the individual patient data confidential. The data may only be shared within the team conducting the analysis for the approved project. Requests from other individuals for access to the data should be referred to the NRG Oncology Data Sharing Requests Review Coordinator.
5. The procedures and regulatory requirements discussed in Sections A and B must be met.
6. NRG Oncology does not make the authority to approve the content of abstracts or manuscripts is a condition for use of shared data. However, the investigator must agree to submit copies of all abstracts and manuscripts arising from the project to the NRG Oncology Data Sharing Requests Review Coordinator.

7. In some situations, a fee may be charged to cover the expenses associated with the development of the data file containing the requested data. If applicable, this fee must be received before data for an approved request will be provided to the requesting investigator.

D. Appeal Process

1. If the data are available and can be provided in accordance with all regulatory and legal restrictions, a request for data that is denied can be appealed by the applicant.

2. The appeal will be reviewed by the Group Chairs, the responsible NCI Program Officer, and an outside statistician. The statistician will be named jointly by the Group Chairs and the NCI Program Officer.

IV. References

- NRG Oncology Data Request Application Form (https://www.nrgoncology.org/Resources/Ancillary-Projects-Applications)

V. Appendices

Investigator Responsibilities Agreement Form

VI. Regulations and Guidelines

- NIH Data Sharing Policy and Implementation Guidance
- Model for NCTC Program Data Sharing Policy for Network Group Operations Centers & Network Group SDMCs
INVESTIGATOR RESPONSIBILITIES AGREEMENT FORM

STUDY TITLE: __________________________________________

INVESTIGATOR: _________________________________________

Return to: APC@nrgoncology.org together with the Data Request Application Form

By signing below, I agree/certify that:

1. I will maintain current and accurate records of research data.

2. I am cognizant of and will comply with current Federal Regulations and IRB requirements governing human subject research.

3. I will conduct this research in strict accordance with the research proposed in the application and will use the data provided by the NRG only for the approved research. If I wish to use the data for another research project, a new request must be submitted for approval by the NRG Oncology Data Sharing Requests Review Coordinator.

4. I will notify, in writing, the Data Sharing Requests Review Coordinator of any modification of the research protocol originally submitted; and, if necessary, I will request and obtain IRB approval of any modification to the research protocol.

5. I will not share the data provided by the NRG Oncology with any other individuals except co-investigators who are working directly with me to analyze the data. Requests for access to the data from any other individuals should be referred to the Data Sharing Requests Review Coordinator.

6. I will ensure that all members of my research team assisting in the conduct of this research study have been provided a copy of the entire current version of the research application.

7. Neither I, nor any members of my research team, will attempt to access any link to the human subjects who were involved in the study from which data are provided.

8. Neither I, nor any members of my research team, will attempt to interact with human subjects who were involved in the study from which data are provided.

9. I will respond promptly to all requests for information or materials solicited by the Data Sharing Requests Review Coordinator.

10. At the time of data receipt from the NRG Oncology I will confirm, in writing, to the Data Sharing Requests Review Coordinator that I have received the data and I will provide a date that I anticipate study completion of my analysis.

11. Approval of a manuscript or abstract is not a condition for use of the data, but I will submit to the Data Sharing Requests Review Coordinator a 30-day advance written notice of submission of a manuscript or abstract, along with a draft copy of the manuscript or abstract.

12. In any presentation or publication of results associated with the data provided by the NRG Oncology I will acknowledge the NRG’s role in providing data and include an acknowledgement/disclaimer of the NCI as required by the applicable NCI grant relevant to the NRG Oncology data that was provided to me.

13. I will provide Data Sharing Review Panel Coordinator with a copy of the published abstract or manuscript within 30 days of publication.

Investigator Signature: ________________________________ Date: ____________

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