NRG Oncology Patient Follow-Up Data Submission Policy

Version 1: October 13, 2020

I. Introduction

Collection and submission of follow-up data are an important component of NRG Oncology research as follow-up data are required to answer the research study endpoints.

II. Scope

All institutions and individuals participating in NRG Oncology research are responsible for the follow-up of all patients registered by the institution and/or the individual at the institution for as long as the patient remains alive or as per the protocol specified length of time.

III. Procedures and Process

The following describes the process to be observed by all NRG Oncology (NRG) member sites regarding follow-up of patients registered to NRG protocols:

1. The commitment to patient follow-up remains regardless of the membership status or funding status within NRG.

2. If patient care is conducted at multiple institutions, the institution credited with the patient registration is responsible for follow-up *unless* the patient has been transferred to another institution, in which case the receiving institution becomes responsible for follow-up.

3. If an institution ceases to be an NRG member, the institution retains responsibility for the treatment and clinical management of all patients currently receiving treatment and active follow-up, and is to provide necessary data forms and follow-up information, including responding to queries.

4. If an investigator changes affiliation from one NRG institution to another NRG institution and the patient follows, the investigator takes with him or her responsibility for future follow-up of the patient and the patient is to be transferred to the new institution per # 7 - 8.

5. If an investigator changes affiliation from one NRG institution to another NRG institution or leaves an NRG institution and the patient does not follow the investigator, follow-up responsibility is to be transferred to another active investigator at the institution who knowingly accepts such responsibility.

6. If an investigator moves from an NRG institution to another Institution which is not an NRG Institution and the patient follows the investigator, it is the responsibility of the Investigator to provide information to the NRG Institution to continue all data submission. This includes follow-up information and response to queries.

7. Notification of transfers of follow-up responsibility for patients that were not registered through the Oncology Patient Enrollment Network (OPEN) must be made using the processes of the Legacy Group. If the patient was registered through OPEN, the patient transfer will need to be initiated using the OPEN Transfer and Update Module (T&UM).

8. If follow-up responsibility is transferred to a new institution, verification of IRB oversight is required. The new institution must have current IRB approval of the protocol prior to accepting a transfer of a new patient that is currently on treatment.

   It is strongly recommended that the receiving institution receive a copy of the research record(s)

from the transferring institution and ensure all outstanding expectations and queries have been resolved prior to signing the transfer form. The transferring site must provide CRFs for resolution of queries for any data obtained prior to the acceptance date.

9. NRG studies which are no longer collecting data are listed with a status of “Terminated” on the NRG website at https://www.nrgoncology.org/Clinical-Trials/Protocol-Search.

10. Member institutions are able to reference NRG Data Management guidance and other resources related to follow-up posted on the NRG Oncology website here: Link.

NOTE: This policy applies only to studies coordinated by NRG Oncology.

APPROVED: October 13, 2020 NRG GROUP CHAIRS MEETING

DUE FOR REVIEW: October 2022