Introductory Materials for NRG Oncology Clinical Trial Coordinators

This packet was designed to make your introduction to the NRG Oncology as smooth as possible by providing you with information regarding specific processes and contacts to be used when conducting NRG Oncology clinical trials. The information that follows is intended to assist you in understanding how NRG Oncology trials operate and who to contact when you have questions or difficulties.

Table of contents

The NRG protocol document and the NRG Oncology website should be used as the primary source for protocol directions and information. Supporting documents and other provided resources may be used for additional reference.
Table of Contents

I  NRG Oncology Overview
II NRG Oncology Website
III NRG Oncology Contacts
IV NRG Oncology Committees
V CRA and CTN Information Sources
VI NRG Oncology Membership and Roster Changes
VII NRG Oncology Semi Annual Meetings
VIII Acronyms
IX Frequently Asked Questions
NRG Oncology (NRG) Overview

NRG Oncology (NRG) brings together three legacy cooperative groups: the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG). Cumulatively, these groups represent over 150 years of practice-defining research. Each legacy group maintained a website incorporating vast amounts of information and important links related to the specific cooperative group studies, reference guides and resources, support staff and rosters, study publications, other educational opportunities, etc. The legacy groups of NRG (N=NSABP, R=RTOG, G=GOG) still maintain their respective websites with valued information for all members of the research team.

NRG Oncology Mission Statement

NRG Oncology seeks to improve the lives of cancer patients by conducting practice-changing multi-institutional clinical and translational research with emphases on gender-specific malignancies including gynecologic, breast, and prostate cancers and on localized or locally advanced cancers of all types.

Clinical Trial Network Categories

Cooperative Group:
A research network program of ten decentralized “cooperative” groups created in 1955 to promote and support clinical trials throughout the United States, Canada and Europe. The groups worked with National Cancer Institute (NCI) to identify important questions in cancer research and to design clinical trials to answer these questions. This program was restructured in 2014 and is now called National Clinical Trials Network (NCTN).

National Clinical Trials Network (NCTN)
The NCTN is the consolidation and transformation in 2014 by the NCI of the nine former adult cooperative groups into five U.S. network groups and the Canadian Collaborating Clinical Trials Network. It is a network to enhance collaboration of national cancer clinical trials research activities and to fulfill the promise of precision cancer medicine.

Lead Academic Participating Site (LAPS)
LAPS is a designation that is tied to grant money and indicates a specific funding source. This designation was created specifically for the NCTN. Thirty U.S. academic institutions were selected to receive LAPS grants based on their ability to enroll a high number of patients onto NCTN trials along with demonstrating scientific leadership in the design and conduct of clinical trials.

NCI Community Oncology Research Program (NCORP)
NCORP (formerly CCOP) is a system that was developed in 2014 to support clinical trials research in the community setting. NCORP will play a critical and complementary role to the NCTN involving both cancer treatment and cancer care delivery research.
NRG Oncology Legacy Groups

National Surgical Adjuvant Breast and Bowel Project (NSABP)

NSABP trials have had a profound impact on the treatment of breast and bowel cancer and on the understanding of the biology of these diseases. The group is perhaps best known for its series of surgical breast cancer studies that led to the elimination of the radical mastectomy and the confirmation that lumpectomy plus radiation therapy (RT) is an effective option for most women with invasive or noninvasive breast cancer. The NSABP also conducted a series of adjuvant therapy trials which evaluated systemic treatments for patients with node-positive, node-negative, and ductal carcinoma in situ (DCIS) breast cancer as well as a series of adjuvant therapy trials for patients with colon and/or rectal cancer. Many of today's standard adjuvant therapy regimens result directly from these trials. NSABP research was central to the development of the oncotype DX® tool for assessing recurrence risk and predictive significance of chemotherapy in women with early-stage, hormone receptor-positive cancer. Neoadjuvant therapy for the treatment of operable breast cancer, a current research focus of the group, is an approach that allows for high breast preservation and tumor down staging rates and provides serial tumor specimen collections for early response assessment. The NSABP Biorepository houses tissue blocks, serum, and lymphocytes from more than 70,000 patients entered into NSABP breast and colorectal cancer trials and represents a valuable resource for current and future correlative science efforts for these diseases.

Radiation Therapy Oncology Group (RTOG)

RTOG research has set and/or validated many of the national and international standards for combined modality therapy of localized to intermediate-stage cancer in adult brain tumors, head and neck cancer, breast cancer, localized or locally advanced lung cancer, non-colorectal gastrointestinal cancer, genitourinary cancer, and localized and locally advanced prostate cancer. A number of recent RTOG-led trials have defined new practice standards: the first randomized brain tumor trial defining chromosomal deletions as prognostic and predictive biomarkers; the first phase III trial defining concurrent chemoradiation as the standard of care for laryngeal preservation; the phase III trial helping to decrease overtreatment by demonstrating the lack of survival benefit for routine inclusion of surgery in management of patients with mediastinal lymph node-positive non-small-cell lung cancer (NSCLC); and a series of trials clarifying the role and optimal duration of total androgen blockade for men with localized, locally advanced, or locally recurrent prostate cancer.

Gynecologic Oncology Group (GOG)

GOG embodies the only significant effort in the current cooperative group system to study gynecologic cancers and is regarded internationally as the leader in clinical trials in this domain. GOG research has yielded many practice-defining advances in the management of gynecologic cancers. While defining the current international standard of care for women with advanced ovarian cancer, GOG established intraperitoneal chemotherapy as the treatment of choice in the management of small-volume residual advanced ovarian cancer. In addition, GOG studies identified concurrent cisplatin-based chemo-RT as the treatment of choice for stages IB2-IVA carcinoma of the uterine cervix while evolving the current treatment of choice for advanced or recurrent carcinoma of the cervix.
studies defined the spread pattern of endometrial carcinoma and changed the paradigm for the management of locally advanced endometrial carcinoma and developed effective combination chemotherapy for advanced or recurrent endometrial carcinoma. This group also set the current standard of care for patients with uterine sarcomas—once thought to be too uncommon to permit large trials—through a series of important phase III studies.

As NRG Oncology, these three strong legacy groups will create a synergy that will have significant impact on the National Clinical Trials network.
NRG Oncology Website

NRG Home Page
The NRG Oncology website home page is available to the public. The website provides description of NRG Oncology and contains information about future research and latest updates on clinical trials endeavors. The NRG Member’s Area provides information for NRG Oncology Members related to NRG Protocols, the organization and Member-specific announcements. The Member Login is located in the upper right hand corner and is the same as your personal CTSU login.

Current Login:
Username: name
Password: CTSU login

Home page tabs
Home: The opening page
About Us: Description of NRG Oncology, the legacy groups, history and mission, vision values
Scientific Program: Information on programs and committees for NRG Oncology
Clinical Trials: A table of NRG Oncology protocols and related information. NRG Publication information is also posted here including NRG Oncology publications, abstracts and Publication/Manuscript policies, guidelines and presentation templates.
Nurses & CRAs: Information about the Protocol Support Groups, CTN and CRA subcommittees and working groups.
Resources: Scientific links to resources of interest to affiliated investigators, site research teams and patients and their families
News: NRG Oncology weekly broadcasts, press releases, newsletters, announcements and notices.
Statistical Reports: Statistical reports are produced and posted on the NRG Oncology website twice a year in conjunction with the biannual NRG Oncology Group Meetings. NRG and legacy trials for which the primary outcome has not been reported are included. (Member only access.)

Additional information found in yellow tabs at the bottom of the page includes:
Membership information: Membership requirements, applications and roster forms; site participation recognition and member institution lists
Meetings: NRG Oncology future meetings, past meeting information and other major scientific meetings
NCORP: NRG NCORP overview of related research.
Patient Advocates: Committee information and resources
NRG Oncology Contacts

Information about and copies of the following can be found in the [NRG Oncology website](https://www.nrgoncology.org) unless otherwise noted.


The NRG Oncology provides many sources of information regarding NRG Oncology protocols as well as contact information. The protocol document is always the first source for protocol directions and information. NRG Oncology supporting resource materials may be used as additional references. The protocol title page, which lists the study team members and contact information, is the initial place to look for the correct contacts for protocol questions.

Currently, NRG Oncology protocols may list contact information differently. Many protocols list a specific phone number or email contact for specific questions. For example, a protocol might list a contact specifically by topic or specialty/role such as: eligibility and clinical questions, regulatory questions, Adverse Event Reporting Nurse or Data Manager, Research Nurse and/or Protocol Coordinator. Some protocols direct all questions concerning both eligibility and data submission to the data manager. Sometimes the contact options are listed only by Protocol Chairs according to their specialty.

When deciding the best contact, consider the type of question.

Clinical questions include:
- Eligibility
- Treatment regimen / dose modifications
- Required tests, exams and other studies
- Patient care management
- Other clinical logistics

Data management questions include:
- Data completion
- Data submission
- Data management
- Data delinquency
- Data notifications/queries

Data management Protocol Contacts and Guidance:
- Lost to Follow-up Guidance Document
- Never Say Lost
- Medidata Rave FAQs
- Routine AE Reporting Guidance Document
For a more expeditious response, remember to provide the following information when you email or leave a message:

- Your name and complete phone number
- Institution name / number
- Your question including the protocol number (if applicable)

Protocol Resources
There are many resources created for your reference including general information about NRG Oncology and NRG Oncology protocols.

Protocol specific resources may include documents that are separate from the protocol document such as protocol guidelines, frequently asked questions (FAQs), pathology instructions, eblasts, fact sheets, memos, newsletters, tools, site initiation visits(SIV), webinars, related slide set presentations as well as protocol promotional materials. These resources are typically posted on the CTSU website under the specific protocol and may be found under the following tab/headings:

- Supplemental Documents
- Education and Promotion
- Case Report Forms (CRFs)
- Miscellaneous

Data Management Resources
Materials available on the NRG Oncology Website include:

- Medidata Rave FAQs
- Routine AE Reporting Guidance Document
- Lost to Follow-up Guidance Document
- Never Say Lost
- Use of Consent Withdrawal Process

Case Reimbursement Questions
Email: payments@nrgoncology.org

Clinical Research Coordinator Mentor Program and Introductory Materials for NRG Oncology Clinical Trial Coordinators

- Mentor Program Description
- Introductory Materials-This packet was developed to provide research staff information regarding specific processes, resources and contacts to assist in understanding NRG Oncology trials processes and instructions.

NRG Oncology General Contact Information
If your question is not covered in any of the resources or contact lists, you may contact NRG Oncology for additional assistance:

Phone: 267-519-6630
Email: info@nrgoncology.org
Legacy Group Information: *(login required)*

**NSABP**

**RTOG**

**GOG**

Protocol Support Committees: *(login required)*

**NRG Oncology Protocol Support Committee (PSC) Members**

**NRG Oncology Protocol Support Committee Clinical Trial Nurse (CTN) Subcommittee Members**

**NRG Oncology Protocol Support Committee Clinical Research Associate (CRA) Subcommittee Members**
NRG Oncology Committees

**NRG Organizational Structure and Overview of Committees:**

**Scientific Core Committees**

Seven scientific core committees will serve as shared resources of expertise and--in some cases--technology, enabling disease site and non-disease site scientific committee investigators to develop and execute high-quality research trials. The leaders and co-leaders of these committees will be appointed by the group chairs and will have membership chosen for expertise applicable to the overall priorities of NRG Oncology, as well as to each of its disease site committees. They include the Pathology Committee, Surgical Oncology Committee, Medical Oncology Committee, Radiation Oncology Committee, Patient Advocate Committee, Special Populations Committee, and Protocol Support Committee.

**Protocol Support Committee (PSC):**

The primary functions of the Protocol Support Committee (PSC) include support and quality control of protocol-related activities, education and training of NRG Oncology members on relevant topics, and mentorship. The PSC includes 2 subcommittees, the Clinical Research Associate Committee and the Clinical Trial Nurse Committee.

This Committee and its subcommittees are your contacts for voicing concerns and requests for support and resources for the Clinical Research Associates (CRAs) and Clinical Trial Nurses (CTNs) in the NRG Oncology. See NRG Oncology Contacts Section of these Introductory Materials for subcommittee member names and contact information.

The Protocol Support Committee (PSC), subcommittees and working groups meet via conference calls and during the semiannual meetings to conduct committee business and work on committee and working group projects.

To help facilitate the goals of these committees, there are four working groups: Education and Training, Mentorship, Protocol Review, and Quality Control.

**Working Groups of the PSC:**

**Education and Training**

This working group will develop educational programs for the CRAs and CTNs attending the NRG meetings, create protocol specific tools to educate research staff about protocol requirements as well as conduct training programs such as new member orientation and protocol training workshops.
Mentorship

This working group will develop a mentor program that will provide individual support from experienced members with the objective of improving the conduct of clinical trials throughout NRG and promoting quality control.

Protocol Review

This working group will review prospectively protocols for clinically relevant matters by identifying any potential patient care issues and anticipating any nursing issues, such as symptom management and therapy administration, which might impact patient compliance. The group will also address potential barriers to protocol accrual.

Quality Control

This working group will identify and promote best practices by focusing on protocol compliance and audit issues. The group will utilize the Mentor Program and NRG educational programs to resolve compliance and data issues.

NRG Oncology Clinical Research Associate (CRA) and Clinical Trials Nurse (CTN) Subcommittees

The CRA and CTN Subcommittees are advisory/working committees under the NRG Oncology Protocol Support Committee (PSC). These groups facilitate the goals NRG and provide support with quality control of protocol-related activities along with education and training of NRG Oncology members on relevant topics and mentorship. The committee meets twice a year at the NRG Oncology meetings and via conference calls as needed.

The following are additional NRG Committees. A description of each committee is located on the NRG Oncology website:

- NRG Oncology Group Executive Committee
- Disease Site Committees
- Non-Disease Site Scientific Committees
- Research Strategy Committee
- Concept Prioritization Advisory Committee (CPAC)
- Publications Committee
- Membership Committee
- Communications Committee
- Audit/Quality Control Committee
- Data Monitoring Committee
CRA and CTN Information Sources

Helpful materials are available to assist you with the NRG Oncology Clinical Trials. The protocol document and related materials are posted on the CTSU website for federally funded/CTEP trials. Ancillary materials should be used as a reference, but should never take the place of the protocol. Most protocol and related documents are posted on the CTSU website.

The following are materials that you may find helpful. They contain general information and may not be protocol and/or NRG Oncology-specific. These materials can be found on the NRG Oncology website unless otherwise specified.

AE Reporting - CTCAE
Adverse events (also known as toxicities, adverse drug reactions, or AEs) are reported on NRG Oncology studies using Common Toxicity Criteria for Adverse Events (CTCAE). These criteria are used to establish the grade or severity of the adverse event so that dose modifications and adverse event reporting can be done in a consistent manner across all clinical trials. Please refer to each protocol to determine which CTCAE version must be used. Further explanation of the CTCAE and copies can be downloaded from the CTSU website.

CTCAE Versions

Translational Research
Research that utilizes knowledge of human biology to develop and test the feasibility of cancer-relevant interventions (to prevent, diagnose, and treat disease) in humans and/or determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer is called translational research. The goal is to “translate” basic research findings into medical practice.

The aim of translational research is to better understand patients’ prognoses, predict responses to specific therapies, and better understand basic sciences. One of the main approaches in current translational research is tissue and serum collection for study. The NRG Oncology has both a Translational Science (TS) Committee and a Biospecimen Banking Committee. One of the NRG Oncology Translational Science Committee’s primary tasks is to oversee the design and implementation of projects related to tissue collection within NRG Oncology. The NRG Oncology Biospecimen Banks Group oversees the management and direction of the NRG Biobanks as well as collection procedures and directions.
Biospecimen Collection and the NRG Oncology Biospecimen Banks (NRG BB)

Biospecimen collections may also be known as translational research, correlative science or pathology studies. The NRG Biospecimen studies may be embedded in the protocol a sub-study or can be written as a stand-alone companion trial. The companion laboratory studies may be developed and written after the activation of a protocol.

Biospecimens can include tissue blocks, tissue slides, and biofluids including serum, plasma, and urine. In order to carry out biospecimen studies, protocols and related documents will contain the following information: directions related to the purpose of the study, as well as the collection, processing, and shipment of the specimens to designated repositories. Be sure to review the protocol or related documents for study requirements and directions related to biospecimen collections for each protocol. Deviations from the instructions (e.g. collection, processing, and shipping) can affect the outcomes of biospecimen research.

After collection and processing of the required specimens at the site, the specimens are sent to a protocol-designated repository (e.g. lab) for storage or to conduct specific studies.

**Mandatory vs. Optional Studies**

Unless otherwise stated in the protocol instructions and activation information, all sites must offer the biospecimen studies to the patients. These biospecimen studies may or may not be mandatory for the patient's study participation. Some biospecimens may be a mandatory part of the study (i.e., if there is a primary endpoint that depends on their analysis or if the specimen is required to determine eligibility or study arm stratification). Furthermore, some studies have a combination of both mandatory and optional specimen requirements. If a specimen collection is not mandated by the study, it still must be offered to and explained to the patient. Therefore, although some biospecimen studies may be optional for the patient, they are not optional for the site. Be sure that the patient understands the biospecimen questions on the consent form and that the ICF is marked by the patient accordingly for all biospecimen studies.

The Clinical Trial Coordinator plays a vital role in ensuring patient understanding of correlative studies during the consent process. Coordinators are key in educating patients regarding the biospecimen collections, requirements and expectations. Likewise, the role of coordinator is essential to the collection and processing of biospecimens. The coordinator and assigned staff may play an active role in collecting, performing, processing, providing specimen collection kits, and explaining specific protocol instructions to the appropriate staff.

In addition to ensuring the biospecimens are collected and submitted at the protocol specified time points, the coordinator's role is equally important in the accurate completion of related paperwork and forms, and the submission of the biospecimen to the protocol specified biobank repository.
NRG Biospecimen Collection and Banks

There are very specific directions for collecting, processing, and submitting of all protocol biospecimens. The specific instructions provide essential information to support the biospecimen studies for each protocol. These instructions should be distributed to staff involved with any aspect of sample collection and submission, including staff at Affiliates/Aligned Affiliates and NCORP Components and Sub-Affiliate or Sub-Components.

The biospecimen and banking instructions may be embedded directly in a protocol or they may be a separate document that is available with all other posted documents. Refer to the protocol and related documents for the specific directions including paperwork required for the specimen submission such as a copy of an Informed Consent Form, submission/transmittal form, pathology report, etc.

Questions regarding kits, collection, preparation, or shipment should be directed to the specified protocol contact.

**NOTE:** Some collection kits need to be ordered in advance.

**Funding Information for Biospecimens**

Specimen collection information should be entered into the CTSU Dashboard tab which will trigger additional funding for specimen submission.

**Safe handling**

All items should be handled using universal precautions and shipped according to the appropriate regulations. Each individual site should have training available in universal precautions and also dangerous goods training required for shipping. Refer to your department of hospital safety for IATA (International Air Transport Association) training for the safe handling and shipping of hazardous materials.

**Cancer Information Resources**

General informational resource links are provided by NRG Oncology to provide a broad range of information about cancer prevention, treatment, and survival. These resources can be accessed through the NRG Oncology website/Resources/Cancer Information Resources.

See the following link for initial *NRG Oncology Biospecimen Collections* information as of July 2015:


Check back in these Introductory Materials for future updates.
Cancer Trials Support Unit (CTSU)
The Cancer Trials Support Unit (CTSU) is a service of the National Cancer Institute (NCI) designed to facilitate access to NCI-funded clinical trials for qualified clinical sites and to support the management and conduct of those clinical trials. CTSU Membership provides access to a wide range of information and support services for qualified investigators and research staff. The CTSU Registration Page provides additional details regarding member access. For those who are not CTSU Members, a listing of active protocols that the CTSU supports along with links to resources for additional information on NCI-funded clinical trials can still be viewed.

CTEP-AERS FAQs

Case Reimbursements (Billing/Funding)

Funding Sheets are included for each individual NRG Oncology protocol as part of the protocol-related documents. Protocol-specific Funding Sheets can be downloaded from the CTSU website under Protocol/funding Information. In addition, please refer to your institutional policies and procedures for further information.

Central IRB (CIRB)
The Central IRB (CIRB) Initiative is designed to help reduce the administrative burden on local IRBs and investigators while continuing a high level of protection for human research participants. CIRB enables an investigator to enroll patients into NCI-sponsored clinical trials significantly faster than when employing the traditional method of IRB review. The CIRB Initiative is sponsored by the NCI in consultation with the Department of Health and Human Services Office for Human Research Protections (OHRP). See the CIRB website for further information:

ClinicalTrials.gov
ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and this site, including relevant history, policies, and laws.

Data Management
Case Report Forms (CRF) Completion and Submission Guidelines for NRG Oncology Trials provide suggestions and explanations about clinical and data management issues related to patient entry, case report forms, TELEforms requirements, follow-up, consent withdrawal, lost to follow-up and off therapy status and data submission. The CRF Completion and Submission Guidelines may be found in the Members’ Area of the Legacy Groups. Protocol-specific CRF instructions are provided for each protocol with its forms/worksheet
instructions which are posted on the CTSU website under Protocols/LPO Documents/Case Report Form Folders.

**FDA Guidance Safety Reporting Requirements for INDs and BioAvailability/BioEquivalence Studies**

**Frequently Asked Questions (FAQs)**

**General Clinical Trial Management FAQs**
A general frequently asked questions document has been developed for coordinators to address common study start up and clinical trial management conduct questions, including general eligibility assessment, data management and reporting, regulatory and membership contacts and resources. Please refer to the “Frequently Asked Questions” section.

**Protocol FAQs**
Protocol-specific FAQs may be provided after a study is open to clarify protocol instructions related to protocol specific contacts, common eligibility, clinical management, data management/form completion and submission questions for a specific NRG Oncology protocol. A contact list for protocol specific personnel may be included.

**Manuals/Guidelines**- NRG manuals and guidelines will be posted as they become available

**NCI Guidelines: Adverse Event Reporting Requirements for Investigators**

**News (Newsletters, Broadcasts, Press Releases, Announcements)**
This section of the NRG Oncology website contains various types of communications related to the NRG's latest updates for the membership and/or public through a variety of communications including: Newsletters, Weekly Broadcasts, Press Releases and Announcements.

Weekly NRG Oncology Broadcasts are the primary source of protocol related updates for the coordinators. Urgent and important information may also be communicated via the "Announcements". Broadcast information is posted on the NRG Oncology website under "News". Access is granted by the lead Research Associate (RA) for your institution as rostered through NRG Oncology. You may contact NRG Oncology Roster at 412-339-5294 or roster@nrgoncology.org for site specific inquiries.

**NRG Oncology Audit Program**
NRG Oncology has a quality assurance audit program with an integral monitoring system in compliance with the guidelines of the Clinical Trials Monitoring Branch (CTMB) of the National Cancer Institute (NCI). The primary purpose of the NRG Oncology Audit Program is as follows: to ensure the quality of clinical trials execution; to verify that the institution and any of its affiliations are in compliance with federal regulatory requirements; and to verify the accuracy of study data; and to enhance education. NRG Oncology institutions are audited at least once every three years (in accordance with NCI guidelines).
NRG Oncology Mentor Program
The purpose of this program is to provide support and guidance to CRAs and nurses who are new to NRG Oncology clinical trials or could benefit from the assistance of an experienced CRA or research nurse to increase or supplement their understanding of clinical trials and NRG processes. This program is most beneficial when the new coordinator has been in his or her new or current position for at least three months. A mentor is not intended to replace a Lead RA, coordinator, orientation, educational or other support systems that are already available at the site. The NRG Oncology Mentor Program is currently in development. Look for additional information in the future NRG Oncology Broadcasts.

Past Meeting Resources
NRG Oncology conducts regular group meetings where scientific sessions and protocol updates for NRG Oncology trials are presented. Available Handouts from these sessions are posted on the NRG Oncology website and are available to you for reference. Past meeting handouts are available for CRAs and Nurses as well as physicians and Scientific Sessions.

Keep in mind that these handouts are appropriate for the version of the protocol that was available at the time of the NRG Oncology Meeting. Amendments and changes to the protocol document, forms and/or other protocol documents may have occurred since the meeting. Therefore, the handouts should be used as a reference, but should never take the place of the protocol.

Patient Reported Outcomes (PROs)
Patient reported outcomes are any report of the status of the patient’s well-being directly reported by the patient without interpretation or intervention by the healthcare giver, family, or significant others. Information reported can be physical symptoms, activities of daily living, emotional and psychosocial. Information is usually obtained through validated questionnaires. The questionnaire can be administered by paper or computer. PROs are administered at time points determined by the protocol. People accompanying the patient should be instructed to not answer any of the questions for them. A quiet, private area is the best environment for patients to complete the questionnaires.

It is extremely important to have the questionnaires completed at the specific time points dictated by the protocol. There may be times that the patient may not feel like completing the questionnaire due to side effects for the treatment or their cancer. This is probably the most important time when the questionnaire should be completed. Explain to the patient the importance of completing the questionnaire. Assistance can be provided by circling the answer the patient tells you to. Do not comment or offer suggestions.

The PROs questionnaires can be located on CTSU website under LPO documents. There are studies that use questionnaires on scantron forms and are ordered through the research base website.
Protocol Cards
The protocol card is a quick reference that has been developed by the CTSU for schema, key eligibility/ineligibility points and special studies required prior to entry. (Always refer to the protocol document for complete information.) A paper copy of the protocol card can be printed from the CTSU website. Protocol Cards are located on the CTSU website under Protocols/ LPO Documents/Education & Promotion.

Protocol Promotion

Physician Fact Sheets
The Physician Fact Sheets have been developed by the CTSU and are intended for promotional use among health care professionals and are NOT to be used as patient educational materials. Physician Fact Sheets are located on the CTSU website under Protocols/ LPO Documents/Education & Promotion.

Clinical Trial Overview Presentations
Clinical trial overview PowerPoint presentations are developed for select NRG Oncology trials. The presentations are intended to help site research teams disseminate information about NRG oncology trials.

Regulatory Affairs (IRB, consent form, and other regulatory issues)
Information regarding completion and submission of the required regulatory documents can be found on the CTSU website under the Regulatory Tab. For many NRG protocols regulatory requirements as well as patient entry information and other requirements can also be found in the protocol document and in corresponding study memoranda.

Up-to-date study-related information is sent to site investigators and coordinators via NRG Oncology Weekly Broadcasts. The updates such as study closures, amendments, forms changes, and safety information are typically listed under “Protocol Activity” and “Safety Information.” Weekly broadcast are typically sent to sites on Mondays. Special broadcasts may be sent throughout the week. Broadcasts are posted on the NRG Oncology website.

Additionally, the CTSU sends bi-weekly broadcasts, which list protocol updates, amendments, IND reports, and any other information that needs to be processed for all NCTN groups.

You can obtain the updated information/documents by following the links in the NRG Oncology Weekly Broadcast and accessing the protocol-specific pages of the NRG Oncology and CTSU websites. (For older trials some links in the broadcast may take you to the legacy websites [NSABP, RTOG, GOG].) We strongly encourage you to become familiar with the protocol pages on the NRG and CTSU websites.

For sites using the NCI CIRB, IRB approvals are automatically uploaded in real-time to the CTSU. (CIRB sites no longer have to send in continuing review and amendment approvals.) The CIRB no longer sends out bi-weekly broadcasts, so be sure to follow the NRG Oncology and CTSU broadcasts for protocol updates. The CIRB-related documents can be found on the CTSU website under the specific protocol and then the CIRB tab. Please note that not all NRG Oncology studies are reviewed by the CIRB.
To maintain current documents and submission requirements, be sure to find or create a reminder system for routinely checking for new protocol updates in the broadcast and for CIRB-approved documents including annual renewals. For CTSU menu studies, the current version of the protocol is posted on the CTSU website for federally funded/CTEP trials and should always be used as the first and current source of information.

Please note that for updates and information that need to be processed in a time-sensitive manner, the date that the information was distributed in the NRG Oncology broadcast marks the starting date for the time-sensitive activity (e.g., processing of amendments, submitting or notifying information to IRBs).

**NOTE: Be sure that you are working from your institution’s IRB-approved protocol and related documents at your site.**

Regulatory contact information is listed in the protocol. Should you have any questions about the regulatory requirements for a specific NRG protocol, please contact the Department of Regulatory Affairs/Protocol Coordinator as listed on the cover page of the protocol.

*PI, Contact PI, LAPS PI, Local PI, Investigator, Lead RA, Co-lead RA, local lead RA, CRA, RAVE CRA, and other support staff by request.

**Response Evaluation Criteria in Solid Tumors (RECIST)**

RECIST is a reproducible system of measuring tumor burden in investigational subjects often used as a standard in clinical trials.

**Staging Criteria**

Staging describes the severity of a person’s cancer based on the size and/or extent (reach) of the original (primary) tumor and whether or not cancer has spread in the body. Staging is important for several reasons:

- Staging helps the doctor plan the appropriate treatment.
- Cancer stage can be used in estimating a person’s prognosis.
- Knowing the stage of cancer is important in identifying clinical trials that may be a suitable treatment option for a patient.
- Staging helps health care providers and researchers exchange information about patients; it also gives them a common terminology for evaluating the results of clinical trials and comparing the results of different trials.

The TNM system is one of the most widely used cancer staging systems. Most types of cancer have TNM designations, but some do not. For example, cancers of the brain and spinal cord are staged according to their cell type and grade. Different staging systems are also used for many cancers of the blood or bone marrow, such as lymphomas. The Ann Arbor staging classification is commonly used to stage lymphomas and has been adopted by both the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC). However, other cancers of the blood or bone marrow, including most types of leukemia, do not have a clear-cut staging system.
Another staging system, developed by the International Federation of Gynecology and Obstetrics (FIGO), is used to stage cancers of the cervix, uterus, ovary, vagina, and vulva. This system is also based on TNM information. Additionally, most childhood cancers are staged using either the TNM system or the staging criteria of the Children’s Oncology Group (COG), which conducts pediatric clinical trials; however, other staging systems may be used for some childhood cancers.

Check in your physician’s office, medical library, protocol or the specific staging website for the specific details for a particular staging system. Be sure that you check the specific protocol for the required staging system and version.
NRG Oncology Membership and Roster Changes

**NRG Oncology Membership**
Membership categories and requirements are outlined and described on the NRG Oncology Web site under Membership and membership Requirements
http://www.nrgoncology.org/AboutUs/Membership.aspx

**NRG Oncology Member Roster**
Please promptly notify NRG Oncology of any changes in personnel, name of member institutions, payee name, etc. This information is used to ensure that we have current information so that communications can be directed accurately and in a timely manner.

The Roster Update Management System (RUMS) is now in production for NCTN and CTSU sites. Site Administrators must use the Roster Update Management System (RUMS) to review and manage rosters using the screens available on the CTSU website. You can learn how to use RUMS by watching the short videos posted on the CTSU website.

NRG Oncology will only accept roster updates for primary role changes, member type and parent site changes submitted on the appropriate form(s). All forms are available on the NRG Oncology Web site under Membership/Membership Applications & Roster Forms: http://www.nrgoncology.org/AboutUs/Membership/MembershipApplicationsRosterForms.aspx

The submission of the following forms is the mechanism to notify NRG Oncology of any roster changes. These forms are available as both a fillable web-based form and a form that can be printed, completed and submitted.

<table>
<thead>
<tr>
<th>Form</th>
<th>Use to:</th>
<th>Comments:</th>
<th>Questions:</th>
<th>Submit to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person Primary Role Change</td>
<td>Add, remove or change primary roles for person(s) at all sites</td>
<td>Person Roster Roles are provided on the NRG Oncology Web site under Membership. <a href="http://www.nrgoncology.org/AboutUs/Membership/">http://www.nrgoncology.org/AboutUs/Membership/</a></td>
<td>NRG Oncology Roster: 412-339-5292 or <a href="mailto:roster@nrgoncology.org">roster@nrgoncology.org</a></td>
<td><a href="mailto:roster@nrgoncology.org">roster@nrgoncology.org</a></td>
</tr>
</tbody>
</table>

Member Type and Parent Site Changes
### Roster Changes

<table>
<thead>
<tr>
<th>Form</th>
<th>Use to:</th>
<th>Comments:</th>
<th>Questions:</th>
<th>Submit to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parent Site Change Request</td>
<td>Request a Parent site change</td>
<td></td>
<td>NRG Oncology Roster: 412-339-5292 or <a href="mailto:roster@nrgoncology.org">roster@nrgoncology.org</a></td>
<td><a href="mailto:roster@nrgoncology.org">roster@nrgoncology.org</a></td>
</tr>
<tr>
<td>Site Attribute Form</td>
<td>Add or change sites attributes for a Main Member, NCORP, or LAPS</td>
<td><strong>Lead RA is responsible for submitting changes.</strong> Site Attribute Descriptions are provided on the NRG Oncology Web site under Membership.</td>
<td>NRG Oncology Roster: 412-339-5292 or <a href="mailto:roster@nrgoncology.org">roster@nrgoncology.org</a></td>
<td><a href="mailto:roster@nrgoncology.org">roster@nrgoncology.org</a></td>
</tr>
</tbody>
</table>

**Important reminders about making changes in personnel:**

- The Division of Cancer Prevention's (CDP) NCORP-SYS application is the entry point for NCORP institution and person roster changes, thus NCORPs should only use the Primary Role Change Form and the Site Attribute Form.

- All information noted on these forms is available for your viewing in the NCI Regulatory Support System (RSS), except for the attributes listed on the Site Attribute Form. NRG Oncology Membership will periodically provide a listing from RSS of your site attributes to assist you in keeping this information current.
The following list has been created to assist the research staff who is responsible for coordinating new and annual investigator NCI registrations at their site.

Prior to participation in National Cancer Institute (NCI)-sponsored clinical trials, Investigators (i.e., all physicians involved in the conduct of NCI-sponsored clinical trials) must register with CTEP’s Pharmaceutical Management Branch (PMB) of the Cancer Therapy Evaluation Program (CTEP) via the Registration and Credential Repository (RCR). 

Investigators must first register with CTEP’s Pharmaceutical Management Branch (PMB) prior to obtaining a CTEP-IAM account, refer to the Investigator Registration Fact Sheet posted on the CTEP Web site for more information. After RCR registration is complete, Investigators should then register with CTEP Identity and Access Management (IAM), an active user account and current password will provide access to all CTEP and CTSU (Cancer Trials Support Unit) websites and applications. Only physicians, who are registered with the NCI, have an active registration status (NCI Registration number) may order agent from PMB once the trial is approved.

A unique email address, preferably associated to the user’s primary practice site, is required. Due to the requirement to select and answer security questions, the CTEP-IAM account should be requested by the end user, not by an administrative assistant. NCI registration requires annual completion and submission of each of the following items:

1. **Investigator Registration Packet**
   Food and Drug Administration (FDA) regulations and NCI policy requires all investigators participating in any NCI-sponsored clinical trial to register and to renew their registration annually. NCI registration requires annual completion and submission of each of the following:
   - Statement of Investigator Form (Form FDA 1572)
   - Supplemental Investigator Data Form (IDF)
   - Biographical sketch (NCI Biosketch)
   - Human Subjects Protection (HSP)
   - Good Clinical Practice (GCP)
   - Financial Disclosure Form (FDF)
   - Optional, Current Curriculum Vitae (CV)

   The renewal packets and additional information is available online: [http://ctep.cancer.gov/investigatorResources/investigator_registration_packet.htm](http://ctep.cancer.gov/investigatorResources/investigator_registration_packet.htm)

2. **Register with CTEP**
   Investigators (physicians) involved in the conduct of NCI-sponsored clinical trials must register for a CTEP ID number and then create an account through CTEP-IAM. The password for this account must be updated every 60 days. Physicians must re-register annually for the CTEP-IAM account. The CTEP ID number and the NCI investigator number is the same.
Please use the following link for reference for the CTEP-IAM Fact Sheet: https://www.rtog.org/LinkClick.aspx?fileticket=Im6S79JG3H8%3D&tabid=363

NOTE: The NRG Oncology website requires CTEP-IAM password for access to the Members' Area. If the CTEP-IAM account is not maintained access to the NRG Oncology Members' area will not be available.

3. **Ethics Training**
   Most institutions require site-specific ethics training. Check with your institution for your institution-specific ethics requirements for research conduct.
NRG Oncology Semi Annual Meetings

NRG Oncology conducts regular group meetings. Scientific sessions and protocol updates for NRG’s clinical trials are presented. In addition, educational programs for Clinical Research Associates (CRAs) and Nurses working with NRG clinical trials are also offered at the semiannual meetings. These coordinator directed sessions include:

- **Protocol Support Committee Education Session**
  This program presented by headquarters staff, members of the Protocol Support Committee (PSC), CRA and CTN Subcommittees, and guest lecturers focuses on topics relevant to CRAs and Nurses in the clinical trial setting.

- **Introduction to Clinical Trials: Principles of Clinical Trial Management**
  This program is offered to Clinical Research Associates (CRAs) and Nurses who are new to NRG Oncology Clinical Trials and who have been involved in clinical trial procedures for two or less years. This introduction is designed to overview NRG processes and is meant to supplement general clinical trial orientation that a new coordinator receives from their institution/site or other self-directed educational activities. The primary objective is to provide basic information on the National Cancer Institute policy and procedures as well as information required to perform the specific job responsibilities of a Clinical Research Associates (CRA) Clinical Trial Nurse (CTN) when implementing and conducting NRG Oncology clinical trials. Representatives from NRG Oncology Headquarters staff, CRA, and CTN Subcommittees will present information about clinical trial procedures. Special discussion forums will also be conducted to offer a more interactive questions and answers format. Topics addressed include IRB, adverse event reporting, investigational drug management, quality assurance audits, Medidata RAVE, RECIST Criteria, patient screening and enrollment, protocol therapy, and data management.

- **Protocol Support Committee (PSC) General Session**
  This session involves the PSC members discussing the support and quality control for protocol review and other protocol-related activities as well as education and training of NRG Oncology members on relevant topics and mentorship. This session occurs in a business meeting format and offers a great opportunity for NRG CRAs and Nurses to learn about the goals and the status of projects initiated by the PSC to support NRG Coordinators. This is also the format for NRG Coordinators to provide their input and suggestions as an NRG Member.

Past CRA/Nurses Session presentations have included:
- Adverse Event Reporting Systems (AERS)
- Clinical Trials Support Unit (CTSU)
- Investigational Drug Management
- Medidata Rave
• RECIST
Review past meeting handouts posted on the NRG Oncology Web site under Past Resources and/or CRA/CTN Past Meeting Handouts.

Scientific Sessions
Topics on the state of the science, protocol updates, overviews of clinical data and data issues related to NRG trials and other topics are presented covering a vast range of scientific research being conducted by NRG Oncology investigators. Although the target audience for the scientific sessions is physicians; these sessions are open to all attendees and CRAs, Nurses, Data managers and other research professionals and are encouraged to attend.

➢ Disease Specific Scientific Sessions for NRG Trials
These workshops and committee meetings offer a disease specific review of NRG Oncology’s latest research and planned research across ten main disease sites.

➢ Special Programs
Protocol-specific sessions are offered at each meeting and are open to all attendees, including CRAs and Nurses. These protocol-specific sessions include workshops, education sessions, protocol kick-offs and informational sessions. These sessions provide important information about recently activated trials as well as updates and insight for conducting these trials such as recruitment tips, eligibility review and specific protocol procedures instruction for new and accruing NRG clinical trials. A special symposium may be held that includes a multidisciplinary discussion focused on updates to malignancies and treatments.

CRAs and Nurses and are encouraged to attend any sessions of interest with the exception of those marked ‘invitation only’ or ‘closed’. Closed Sessions are for Committee Members only. Check the meeting agenda on the NRG website for agenda topics and special programs descriptions that are offered at the meeting.

Meeting Announcements:
A few months before the meeting, the meeting information, (program agenda, selected session descriptions, registration information, special session fees, hotel information, etc.) will be announced via NRG Oncology Broadcasts and is posted on the NRG Oncology website. Meeting room locations and available handouts will be posted prior to the meeting on the NRG Oncology website. If you have questions about upcoming meetings, please send an email to meeting-reg@nrgoncology.org.
Acronyms
What Do You Mean From A-Z?

- A = Associate
- AB = Associate Basic
- AP = Associate Plus
- ACR = American College of Radiology
- ACRP = Association of Clinical Research Professionals
- AERS = Adverse Event Reporting System
- ASCO = American Society of Clinical Oncology
- ASH = American Society for Hematology
- CAEPR = Comprehensive Adverse Events and Potential Risks
- CAPA = Corrective and Preventative Action
- CCRA = Certified Clinical Research Associate (ACRP)
- CCRC = Certified Clinical Research Coordinator (ACRP)
- CCRP = Certified Clinical Research Professional (SOCRA=Society of Clinical Research Associates)
- CDC = Center for Disease Control
- CFR = Code of Federal Regulations
- CLIA= Clinical Laboratory Improvement Amendments
- CI = Confidence Interval
- CIRB = (NCI) Central Institutional Review Board
- CME = Continuing Medical Education
- COI = Conflict of Interest
- CR = Complete Remission
- CRA = Clinical Research Associate
- **CRC** = Clinical Research Coordinator
- **CRF** = Case Report Form
- **CTCAEv 5.0** = Common Toxicity Criteria for Adverse Events version 5.0
- **CTEP** = Cancer Therapy Evaluation Program (NCI)
- **CTEP-AERS** = CTEP Adverse Event Reporting System
- **CTEP-IAM** = CTEP Identity and Access Management
- **CTMB** = Clinical Trials Monitoring Branch
- **CTN** = Clinical Trial Nurses
- **CTSU** = Clinical Trials Support Unit
- **CEU** = Continuing Education Unit
- **CV** = Curriculum Vitae
- **DARF** = Drug Accountability Record Form
- **DCP** = Division of Cancer Prevention
- **DCTP** = Division of Cancer Treatment and Diagnosis
- **DFS** = Disease Free Survival
- **DHHS** = Department of Health & Human Services
- **DSMB** = Data Safety Monitoring Board
- **DTL** = Delegation Task Log
- **EDC** = Electronic Data Capture
- **EFS** = Event Free Survival
- **FDA** = Food and Drug Administration
- **FDA-1572** = FDA form for Statement of Investigator
- **FWA** = Federal Wide Assurance
- **GCP** = Good Clinical Practice
- **GOG** = Gynecologic Oncology Group
- **HDR** = High Dose Radiation
- **HIPAA** = Health Insurance Portability and Accountability Act
- **HHS** = Health and Human Services (Department of)
- **HR** = Hazard Ratio
- **IB** = Investigator’s Brochure
- **ICF** = Informed Consent Form
- **IMRT** = Intensity Modulated Radiation Therapy
- **IND** = Investigational New Drug
- **IR** = Immune Related
- **IRB** = Institutional Review Board
- **IVR** = Investigator
- **JCAHO** = Joint Commission of Accreditation of Health Care Organizations
- **LDR** = Low Dose Radiation Brachytherapy
- **LOA** = Letter of Agreement
- **LAPS** = Lead Academic Participating Sites
- **LTF** = Lost to Follow up
- **MedDRA** = Medical Dictionary for Regulatory Activities
- **MM** = Main Member
- **NCCF** = National Childhood Cancer Foundation
- **NCI** = National Cancer Institute
- **NCORP** = NCI Community Oncology Research Program
- **NCORP-Sys** = Electronic Management System for NCORP
- **NCTN** = National Clinical Trials Network
• NIH = National Institutes of Health
• NOS = Not otherwise specified
• NPIVR = Non-Physician Investigator
• NRG Oncology = Legacy Groups NSABP, RTOG, GOG
• NRG-BB = NRG BioBanking
• NSABP = National Surgical Adjuvant Breast and Bowel Project
• OAOP = Online Agent Order Processing
• OHRP = Office for Human Research Protection
• ONS = Oncology Nursing Society
• OPEN = Oncology Patient Enrollment Network
• OS = Overall Survival
• PD = Progressive Disease
• PFS = Progression Free Survival
• PID = Patient ID
• PR = Partial Response
• PHI = Protected Health Information
• PI = Principal Investigator
• PMB = Pharmaceutical Management Branch
• PRO = Patient Reported Outcomes
• PSC = Protocol Support Committee
• QOL = Quality of Life
• RCR = Registration and Credential Repository
• RECIST = Response Evaluation Criteria in Solid Tumors
• RPC = Radiological Physics Center
• RSS = Regulatory Support System
• RT = Radiation Therapy
• RTOG = Radiation Therapy Oncology Group
• RUMS = Roster Update Management System
• SAE = Serious Adverse Event
• SGO = Society of Gynecologic Oncologists
• SOCRA = Society of Clinical Research Associates
• SOP = Standard Operating Procedures
• SPEER = Specific Protocol Exceptions to Expedited Reporting
• TRIAD = Transmission of Imaging and Data
• WBI = Whole Breast Irradiation
Frequently Asked Questions (FAQs) about NRG Oncology

Patient Transfer

Q: My patient is moving out of state, how do I find a NRG site that has the protocol open?

A: Begin by accessing the NRG Oncology website, click on Clinical Trials and you will be offered a list of NRG protocols and click on the specific protocol and follow the link listed under protocol documents. An updated list of participating sites will be available.

Q: Is there a form to complete this process?

A: Yes.

Q: Where do I find that form?

A: The electronic form is located on the CTSU OPEN website under the T&UM tab, which you will find just under the top. There are instructions to complete the transfer and a google map option to obtain a list of study participating institutions.

Data Management

Q: What is TRIAD?

A: TRIAD stands for Transmission of Imaging and Data (TRIAD). It is a standards-based system built by the American College of Radiology (ACR) and allows a seamless exchange of images and data for accreditation of clinical trials and registries.

Q: What is RAVE?

A: RAVE is a cloud-based clinical data management system used to electronically capture, manage, and report clinical research data.

Q: What is the difference between patient registration and randomization?

A: Registration involves submitting required forms for enrollment which generally includes eligibility and demographic information. After registration is completed and submitted, the patient is then randomized by computer. The site is notified immediately on the computer screen of the assigned randomization.

Lost to Follow-up
Q: What do I need to do to declare a patient as “lost to follow-up (LTF)”?

A: Research staff must document multiple attempts to locate patient, including telephone calls, email contact (if available), and certified mail. If repeated efforts to contact a patient fails, and the patient has not been seen in clinic, the research staff may declare the patient “lost to follow-up (LTF)”?

Q: What documentation is required to request a patient is lost to follow-up?

A: It is imperative that research staff keep copies of all documentation related to efforts to communicate with patient in the research record.

Q: Is there a form to complete to request a patient is lost to follow-up?

A: Follow the guidelines per study protocol. Documentation of your attempts to contact the patient is often required. Some protocols require a letter to be sent by certified mail.

Informed Consent

Q: What is the purpose of Informed consent?

A: The oral and written consenting process provides pertinent study information with adequate time to allow a patient to make an informed decision concerning their voluntary participation (FDA 21 CFR 50.20).

Q: What documentation is required for informed consent?

A: The patient should receive a copy of the signed consent for their records. Upon the signing of the consent form, the basic elements of the consenting process should be documented (FDA 21 CFR 50.25).

Q: When is reconsent required?

A: When there are changes to the study or important findings, there will be an amendment to the protocol with a change in the study consent forms. Your IRB will direct you to have your existing patients re-consent with the revised consent form or sign an addendum. This process should also be documented.

Off treatment or Consent Withdrawal

Q: What is the difference between “off treatment” and “consent withdrawal”?

A: “Off treatment” refers to either a patient- or physician-driven decision to stop protocol treatment. These patients continue follow up as outlined in the protocol. “Consent withdrawal” refers specifically to patients who no longer wish to be treated or followed under a research study and have exercised to right to discontinue research participation.
Q: Is there a form to complete to notify the Statistics and Data Management Center (SDMC) that a patient is “off treatment” or has “withdrawn consent”?

A: All protocols have forms available to document “off treatment” status. “Withdrawal of consent” forms may also be available.

Q: How do I know what data is required after a consent withdrawal?
A: All data up to the date of withdrawal must be submitted.

NRG Oncology Meetings

Q: How do I know what meetings I should attend as a CRA or CTN?
A: You may register for any meeting that interests you provided that it is not a “closed” meeting.

Drug Accountability

Q: How do we document destruction of leftover study drug?
A: Refer to protocol guidelines. Usually, drug may only be destroyed after a monitoring visit has documented dosing and return of drug.

Patient Enrollment

Q: Who can enroll a patient at my sight?
A: Only staff delegated by the PI is permitted to enroll a patient.

Q: How do I know how to enroll a patient for a particular protocol?
A: Each protocol outlines the elements of eligibility and must be followed precisely.

Funding

Q: Where do I find funding information for a NRG protocol?
A: Information regarding payments is outlined in the NRG Oncology Funding Sheet for each protocol. The NRG Oncology Funding Sheet can be found in the “Funding Documents” section of the protocol page of the CTSU Member website.