RTOG®
RADIATION THERAPY ONCOLOGY GROUP

New Member Information

Welcome to RTOG! Below is information that will help you organize an RTOG program at your institution.

Required Documents – Prior to entering patients on any RTOG study the following must be completed.

- The RTOG **Membership Agreement**: Affiliate and CCOP members must execute a new Member Agreement, Satellite members and CCOP Components must be included in their parent member's agreement via a Member Agreement Amendment. The appropriate agreement/amendment is sent with the membership approval letter and must be executed by both the site principal investigator and an appropriate institutional official and returned to the RTOG Membership Department before your site can begin to enter patients on RTOG clinical trials.
- The **Membership Update Roster Form** is required if you did not submit one at the time of your application. This information will be used to update your Clinical Trials Support Unit (CTSU) roster (link below). See the link below for the form and the form for further instructions.
- **IRB Approval** for each protocol your site wants to participate in must be submitted to the CTSU. Please note that your NCI institution code will be required on the IRB Transmittal Sheet and CTSU IRB Certification form when submitting any regulatory documentation to CTSU. Approval documentation for all *U.S. and Canadian* sites must be faxed to the (CTSU) at 215-569-0206. *International institutions* submit regulatory documentation directly to RTOG using the International REC Certification Form. Links to these forms can be found on the CTSU page of the RTOG Web site.
- **RTOG Password Authorization Form –** An RTOG username & password is required for all physicians entering patients and all research associates registering patients on RTOG protocols. See link below for required form and information.
- An **approved assurance** must be maintained on file with the National Institutes of Health, Office for Human Research Protections (OHRP). If you already have an approved Federal Wide Assurance (FWA) documentation must be sent to CTSU. For information on how to apply, please visit the FWA website at www.hhs.gov/ohrp. Documentation and renewals of assigned FWA numbers for both U.S. and Canadian institutions should be faxed to RTOG at 215-574-0300 and the Cancer Therapy Support Unit (CTSU) at 215-569-0206. FWA documentation for sites outside North America should be faxed directly to RTOG HQ at 215-574-0300 only.
- **Radiological Physics Center's (RPC's) Quality Assurance Program –** Site must be enrolled and agree to perform the quality audits administered by the RPC including remote annual audits of the machine calibration (see link below). Also sites must complete the study-specific credentialing process for advanced technology protocols.

Helpful Information

www.rtog.org – The website offers a wealth of information about RTOG including copies of all active studies, RTOG procedure manuals and policy documents, meeting information, publication lists, committee lists, contact information, accrual lists, and much more. In addition the RTOG Web site is the portal into the Web data entry system and site tools. Below are some of the useful documents found the RTOG Web site.

- RTOG Membership Evaluation Policy & RTOG Bylaws – Contain the rules that govern RTOG membership
- Protocol Table – You can search for a protocol by number, site, phase or key work. Click on the protocol number to access a summary page with all of the protocol-specific information including reimbursement, headquarters contacts, forms, and the complete protocol document.
- Procedure Manual - This will help you become familiar with RTOG policies and procedures
- Case Credit and Reimbursement Schedule is available from the summary page for each protocol.

- RTOG RA Resources – A link on the Home page takes you to resources for RTOG Research Associates including the schedule of upcoming RA Orientation Sessions. ***RTOG offers training for field research associates four times each year***: at the June semiannual meeting and three times during the year at RTOG Headquarters in Philadelphia. Participation in a training session by a research associate from your site is essential for successful participation in RTOG clinical trials.
- Semiannual Meeting Information including future meeting dates, the current meeting book containing study progress reports, and online meeting registration

RTOG Broadcast List – Join the RTOG Broadcast List to receive up-to-date information on protocol activations and amendments, member news, meeting announcements and more. CCOP members should also sign up to join the **RTOG CCOP Broadcast List**. Canadian members should also sign up for the **Canadian Broadcast List**. To add addresses to any of these lists send an e-mail to RTOG_UserAccounts@acr.org.

RT Credentialing – Information regarding study specific RT credentialing and registration procedures can be found in Section 5.0 of each protocol. Please familiarize yourself with this section of the protocol and all pre-registration requirements before calling to register a patient.

International Site Information – International sites must submit an **International Member Letter of Intent (LOI)** to participate prior to submitting any study to their local regulatory authority. A written response from RTOG HQ confirming the availability of the study to the respective country is required before proceeding with participation. Formal Approval of the LOI will be received via e-mail with important specific instructions for moving forward.

Investigational Study Drugs – There are three ways that drug is supplied for studies involving a drug component: commercially available, supplied by the NCI's Pharmaceutical Management Branch (PMB), or supplied by a pharmaceutical sponsor. Section 7.0 of the protocol provides detailed information about supply and distribution of the study agent. Investigators participating in RTOG trials must register as an investigator with the NCI and receive an NCI investigator code. This information is detailed in Section 14.0 of the **NCI Investigator Handbook.** If the NCI is supplying the drug for a study, they will also provide an Investigator Brochure as applicable. The PMB IB Coordinator can be reached at ibcoordinator@mail.nih.gov or (301) 496-5725. PMB maintains **Policies and Guidelines for Investigational Agents**. Information and the associated NCI forms can be found at their Web site.

For trials in which a pharmaceutical sponsor supplies the study agent, a Study Agent Shipment Form (SASF), which can be found on the protocols page of the RTOG website in the second column next to the specific protocol number, must be submitted to CTSU for all U.S. and Canadian sites, as soon as the individual responsible for the drug has been identified. This is a pre-registration requirement. Submission of this form does not trigger drug shipment; registration of the patient is usually the trigger. **International Institutions submit the SASF directly to RTOG HQ.** Information regarding where to send the SASF will be detailed on the SASF and in the protocol.

Who to Contact

Auditing Elaine Boyle	eboyle@acr.org	215-574-3161
Biospecimen Resource – UCSF	rtog@ucsf.edu	415-476-7864
Broadcast Lists	RTOG_UserAccounts@acr.org	215-574-3224
Case Reimbursement & Credit	RTOG_Membership@acr.org	215-574-3173
Drug Distribution Marie D'Amico	mdamico@acr.org	215-574-3185
Passwords	RTOG_UserAccounts@acr.org	215-574-3224
Patient Eligibility & Data Submission Questions Marianne Yachinsky	myachinsky@acr.org	215-574-3214
PMB IB Coordinator	ibcoordinator@mail.nih.gov	301-496-5725
Regulatory Documents The CTSU Regulatory Office	CTSURegOffice@ecogchair.org	215-789-3652

Roster Changes	RTOG_Membership@acr.org	215-574-3173
RT Credentialing Tammy McGlade	tmcglade@acr.org	215-574-3219
Semiannual Meeting Information Michelle Buado	mbuado@acr.org	215-574-3224
Web Support	websupport@acr.org	800-227-5463 x 4189 215-574-3189

Important Links

RTOG Bylaws: http://www.rtog.org/LinkClick.aspx?fileticket=G0GWDopb4-o%3d&tabid=99
Membership Evaluation Policy: http://www.rtog.org/ LinkClick.aspx?fileticket=AwWWIYx6XSE%3d&tabid=217
New Member Information Sheet: http://www.rtog.org/ LinkClick.aspx?fileticket=6-E7uvPNhEM%3d&tabid=217
RTOG Roster Update Form: http://www.rtog.org/ LinkClick.aspx?fileticket=q61ShTwNbFQ%3d&tabid=217
RTOG Password Authorization Form: http://www.rtog.org/ LinkClick.aspx?fileticket=-BXerpBu5AQ%3d&tabid=219
Protocol Look-up Table: http://www.rtog.org/ ClinicalTrials/ProtocolTable.aspx
Protocol List: http://www.rtog.org/ LinkClick.aspx?fileticket=vDLx6U0EUjs%3d&tabid=180
Case Credit & Reimbursement Schedule: available via the study summary page for each protocol
RTOG Procedure Manual: http://www.rtog.org/ LinkClick.aspx?fileticket=WDSHTqDEobQ%3d&tabid=164
RTOG RA Resources: http://www.rtog.org/ ResearchAssociates/Welcome.aspx
RTOG Audit Manual: http://www.rtog.org/ ResearchAssociates/QualityControlSiteAudits/RTOGAuditManual.aspx
International Member Letter of Intent (LOI): http://www.rtog.org/ LinkClick.aspx?fileticket=0tMdct9KHSs%3d&tabid=117
Radiological Physics Center's (RPC's) Quality Assurance Program: http://rpc.mdanderson.org/rpc/.
Drug Request Form 986: http://ctep.info.nih.gov/forms/index.html#requistion
NCI Investigator's Handbook: http://ctep.info.nih.gov/handbook
Pharmaceutical Data Sheets: http://dtp.nci.nih.gov/docs/idrugs/chembook.html
PMB's Policies and Guidelines for Investigational Agents: http://ctep.cancer.gov/branches/pmb/agent_management.htm
Protection of Human Subjects and the Office for Human Research Protections: www.hhs.gov/ohrp/policy
CTSU Documents: http://www.rtog.org/members/ctsu.html
RTOG Semiannual Meeting Information: http://www.rtog.org/ Meetings/Welcome.aspx