



## **Instructions for online TACT Study Site Training/New Site Staff Training**

TACT now offers on-line study training for new sites entering the trial and all new investigators and coordinators joining an existing TACT site. Training should be completed in sequential order as indicated below. **On-line training must be completed within 2 weeks of your site activation and/or assignment of new personnel.** The appropriate documentation for completing the training must be submitted to the Clinical Coordinating Center as indicated below. If you have any questions please contact Research Assistant, Laura Davila at (305) 674-2703 or at [ldavila@msmc.com](mailto:ldavila@msmc.com).

### **A. Office of Human Research Protections Training.**

- To complete training, please visit the website:  
<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>
- Click on the second link, entitled "Human Participant Protections Education for Research Teams." You are asked to create a new user.
- Complete the 6 modules: 'History,' 'The Basics,' 'Informed Consent,' 'IRB Review,' 'Ongoing Protection,' and 'International Research.'
- At the end of each module there is an 'Exercise' link that is to be answered.
- When you have completed the exercises for all the modules, fill out the course evaluation and print your Certificate of Completion; fax this certificate to the CCC and place a copy in your study regulatory binder training section.
- The web course should take an estimated 1 hour and 15 minutes to complete.
- All TACT personnel on site are to complete this training.

### **B. Clinical Trial Network (CTN) Best Practices Modules.**

- This Clinical Research Introduction online training program can be accessed by following this link: <https://www.ctnbestpractices.org/edu/cmeceu/jim>.
- This 12-module presentation presents the history of clinical research and introduces some of the basic processes and regulations.
- Only Modules 3-12 are required. Modules 1-2 are optional. Complete the Review questions at the end of each module. You may print and save the results.
- At the end of the training return to the first page of the Clinical Research Introduction and click on the Evaluate This Training Program link. Be sure to select the TACT checkbox when you complete this evaluation. If you complete all 12 modules you will receive 0.33 CEUs.
- The web training for CTN Best Practices Modules should take an estimated 2.5 hours to complete.
- The Site Investigator and the Site Coordinator are required to complete this training.

### C. Real Cast Study Training

- The preparation offered with the Real Cast Training provides the necessary components and instructions of the TACT study, such as: who are the key players, what is expected, and other such criteria. The **TACT Starter Kit** (shipped when new sites have completed all the Regulatory document requirements) should be available as a reference when viewing the videos.
- To complete this training, please visit the following website:  
<http://www.realcastproductions.com/sinai/>.
- You are asked to enter your site number, first name, last name, and email address.
- You are required to view the first 11 of the 13 presentations; the remaining two by Allan Magaziner and Steve Hussein are optional.
- When viewing has been completed; download, complete, and print the ‘Certificate of Completion.’ Indicating others who viewed the presentation with you; and fax it back to the CCC and place a copy in your study regulatory binder training section
- This training should take a total of 3 hours.
- All personnel who sign the ‘Site Responsibility and Signature Log’ are required to fulfill this training.

### D. Electronic Data Capture (EDC) Training.

- The Duke Clinical Research Institute will guide you through this training. **PLEASE CONTACT YOUR REGIONAL COORDINATOR PRIOR TO VIEWING! This training requires a user ID and password to access TrialMaster™ (data base system).**
- This training will demonstrate how to enter patient data into an electronic/ internet Case Report Form (eCRF/ iCRF).
- You can access the training modules at: <http://www.tactnih.com> username: infusion, password: tactnih, then click on TACT Training Materials where you will find the TrialMaster® (EDC) Training Modules.
- EDC training is “self-paced” so that users can start or stop at will and resume.
- All site personnel who will enter patient data into the TrialMaster system will need to complete this training.

Training	Where to Find It?	Who Needs Certificate?	Length of Time
OHRP	<a href="http://cme.cancer.gov/clinicaltrials/learnin g/humanparticipant-protections.asp">http://cme.cancer.gov/clinicaltrials/learnin g/humanparticipant-protections.asp</a>	All TACT personnel on Site	1 hour + 15 min
CTN	<a href="https://www.ctnbestpractices.org/edu/cme ceu/jim">https://www.ctnbestpractices.org/edu/cme ceu/jim</a>	Site Investigator and Site Coordinator	2 hours + 30 min
Real Cast	<a href="http://www.realcastproductions.com/sinai/">http://www.realcastproductions.com/sinai/</a>	All persons who signed the ‘Site Responsibility and Signature Log’	3 hours
EDC	<a href="http://www.tactnih.com">http://www.tactnih.com</a>	TACT Site member who will enter data	Self-paced