



Trial to Assess Chelation Therapy (TACT) Instructions for Completion of Regulatory Documents

The TACT regulatory documents described below are available at <http://www.tactnih.com> in the Regulatory Requirements section of the website. These regulatory documents must be sent to the TACT Clinical Coordinating Center (CCC) and reviewed prior to site approval. Copies must be filed in your site Regulatory Binder in the designated sections (review Regulatory Binder Table of Contents)

Please send all regulatory documents to the CCC:

Trial to Assess Chelation Therapy
Research Assistant
Mount Sinai Medical Center
4300 Alton Road, Butler Building
Miami Beach, FL 33140

NOTE: Some documents require an ORIGINAL to be sent via USPS mail to the CCC. NO FAXES or EMAILS will be accepted.

1. Memorandum of Agreement

- **2 original** Memoranda of Agreement (MOAs) signed by the Site Investigator.
- Upon execution, 1 of the MOAs will be returned to your site. File this copy in the appropriate section of your Regulatory Binder.

2. Informed Consent Form (ICF)

- **Copy** of the IRB (Institutional Review Board) approved ICF. The ICF must be stamped with the IRB approval date, or the IRB approval letter (described below) must indicate the ICF version date that was approved by the IRB. Keep original version of the approved ICF in your Regulatory Binder.
- The ICF must have the version date on each page.
- A sample ICF is found on the website. All changes made to the ICF must be pre-approved by the CCC prior to submitting to the IRB.

3. IRB Approval Letter

- **Copy** of approval letter(s) on IRB or institutional letterhead.
- Letter(s) must be signed and dated by IRB chairperson or co-chair.
- Protocol, informed consent, advertisements, or other items reviewed by the IRB must be referred to by name in the approval letter.
- **Keep original IRB approval letter(s) in your Regulatory Binder.**

4. Federalwide (FWA)

Each clinical site must have either an FWA number that is assigned by the Office for Human Research Protections (OHRP), an agency of the federal government. **If your clinical site does not have an FWA number, please complete and then fax or e-mail the FWA application form, found in the Regulatory Requirements section of the TACT website, to Research Assistant, at the CCC.** They will contact you with any corrections that need to be made to the application form. Once approved by the CCC, you will be asked to mail an original FWA application with original signature to Research Assistant at the above address.

If you do not have an FWA number, following are instructions on obtaining one:

- FWA Submission Instructions:
 - Section 1: Enter in the legal name of the institution.
 - Section 2: Enter any additional legal names associated with your site.
 - Section 3: Check the appropriate box.
 - Clinical sites using Sterling IRB should check the box next to “The Belmont Report.” To view The Belmont Report, please click on the following link: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>.
 - Clinical sites using a local IRB need to ask their local IRB what “Statement of Principles” is used by that IRB, and check the appropriate box.
 - Section 4: This section is optional.
 - Section 5: Enter the IRB Registration Number associated with your IRB.
 - Clinical sites using Sterling IRB should enter the Sterling IRB Registration number, **IRB00001790**, and “Sterling Institutional Review Board” in the appropriate boxes.
 - Clinical sites a local IRB should enter the IRB Registration number and officially registered name of their IRB in the appropriate boxes.
 - Section 6: Enter the name of the individual who is responsible for answering questions regarding patient’s rights.
 - Section 7: Enter the name of the individual who is legally authorized to sign for the institution (usually a President or CEO).
- Approximately 3 weeks after submission of the FWA application form, the OHRP will contact you via e-mail to provide your site-assigned FWA number. Place a copy of the document indicating your site-assigned FWA number in your Regulatory Binder.
- All IRBs must be registered. If your IRB is not registered, then you must complete the IRB Registration form, found in the Regulatory Requirements section of the TACT website.

5. Protocol Signature Page

- Currently there are two Protocol signature pages. One for the Protocol dated May 30, 2003 and one for the Protocol dated February 17, 2004.
- **Original** protocol signature page signed by the Site Investigator (no specific date is listed on the form).
- **Original** protocol signature page signed by the Site Investigator for protocol dated Feb. 17, 2004
- Each time there is a Protocol revision a new protocol signature page must be signed by all investigators.

6. FDA form 1572

- **Original** 1572 with authentic signatures by the site investigator.
- Do not use white out on the form.
- There are 2 versions of the 1572 on this website; one for sites using the central IRB and one for sites using a local IRB. Please make sure that you fill out the appropriate form.
- Enter the address of the infusion location in box 3. (Post office box numbers cannot be used. All addresses must be street addresses). If you plan to conduct the trial in more than one location, please make sure that all addresses of infusion locations are listed in box 3 of the 1572. Enter the address of the location where urine dipsticks will be administered in box 3.
- Enter your **assigned** Quest laboratory address in box 4.
- If there are Site Sub-Investigators at your clinical site, all Site Sub-Investigators must be listed in box 6 of the 1572.
- Complete all sections of the 1572.

7. Financial Disclosure

Original signed Financial Disclosure Form for each Site Investigator and Site Sub-Investigator.

8. Conflict of Interest Form

- **Original** Conflict of Interest Form for each Site Investigator and Site Sub-Investigator. A new conflict of interest form must be signed every year by each Site Investigator and Sub-Investigator.

9. CV of Site Investigator all Site Sub-Investigators

- Current **copy** of CV.
- CV of the Site Investigator must include medical license number. In addition, the address listed in section 1 of the FDA form 1572 must match the address listed on the Site Investigator's CV.

10. Laboratory Information

- Lab normal values for the QUEST lab your clinical site will use must be included in your Regulatory Binder. A downloadable and printable file containing this information is included on the TACT website. You do NOT need to send this information to the CCC.
- The laboratory accreditation certification will be sent to you from Quest.
- Guidelines for Abnormal Lab Results are posted at the TACT website, please print and include these in your Study Manual.

11. Training Certificates for Human Protection in Research

- **Copy** of completion certificate for training in Human Protection in Research.
- All clinical site personnel participating in TACT as indicated by your Site Responsibility and Signature Log (described below), must complete this federal government-mandated training. Go to <http://cme.cancer.gov/c01/> to complete the training.
- Print the completion certificate(s) and send copy(ies) to the CCC, file the original(s) in your Regulatory Binder.
- **ANY NEW PERSONNEL WORKING ON THIS TRIAL MUST COMPLETE THIS TRAINING IMMEDIATELY**

12. OmniComm Site Information Sheet – TrialMaster

- **Copy** of the OmniComm Site Information Sheet that includes information about your computer and Internet connection.

13. Site Responsibility and Signature Log

- **Copy** of Site Responsibility and Signature Log that lists **all** personnel taking part in TACT, and their responsibilities.
- Leave the section of the form titled "site number" blank. This will be filled in at a later date once your site number has been assigned.
- **Each time new personnel is added to your site, OR current personnel's responsibilities change your site MUST send an updated log to the CCC**

14. Electronic Signature Authorization Form

- **Original** of Electronic Signature Authorization Form with authentic signature of the Site Investigator (only the Site Investigator is required to complete and sign this form).

15. Professional History Form

Original -of the Professional History Form is required for all site investigators not using Sterling IRB and for all sub-investigators who use both Sterling IRB and local IRB. The reason for this is because this information is already collected for site investigators using Sterling IRB.

16. Screening Logs

- Once your site obtains IRB approval begin screening your patient charts for eligibility for the trial. Complete a screening log and FAX to the CCC at 305-674-3970.

YOU MUST NOTIFY THE CCC IN WRITING IF YOUR SITE'S INVESTIGATOR OR COORDINATOR WILL BE CHANGING AT ANY TIME DURING THE STUDY PERIOD.

CONTACT TACT CCC AT (305) 674-2162OR tactnih@msmc.com WITH ANY QUESTIONS.