



## **Trial to Assess Chelation Therapy (TACT) Instructions for Submitting IRB Materials to the Central IRB for TACT: Sterling IRB**

In order to participate in TACT, each clinical site must obtain approval from an institutional review board (IRB). There are two types of IRBs: 1) "local IRB," an IRB that is associated with a particular physician's office or hospital, or 2) "central IRB," an independent IRB that serves clinical sites that do not have a local IRB. The TACT Clinical Coordinating Center (CCC) has contracted with Sterling Institutional Review Board to serve as the central IRB for the trial. Accordingly, Sterling IRB will serve as the IRB for TACT clinical sites that **do not have an affiliation with a local IRB**. For further information regarding Sterling IRB, please visit their website at [www.sterlingirb.com](http://www.sterlingirb.com).

Listed below are the documents that must be submitted to Sterling IRB for approval of your clinical site. Please send all documents to:

Sterling Institutional Review Board  
6300 Powers Ferry Road  
Suite 600-351  
Atlanta, GA 30339

### **Documents to Submit to Sterling IRB**

#### **Original documents that you provide:**

- 1) Curriculum Vitae of Site Investigator (includes list of previous clinical research experience and publications)
- 2) Copy of Site Investigator's current medical license with expiration date (wallet card acceptable)
- 3) Curriculum Vitae of Sub-Investigator(s)
- 4) Copy of CCC Approved Advertisement(s) / Recruitment Material(s). The study has Sterling approved ads customizable available in the TACT Recruitment Tools and Advertising section of the TACT website ([http://www.tactnih.com/index\\_rec\\_tool.htm](http://www.tactnih.com/index_rec_tool.htm)). You will need to re-submit these ads to the CCC and to Sterling IRB for approval if you make any changes to the text and/or pictures. You will not need to re-submit these ads if you are only adding your address and contact information.

#### **Documents found on TACT website [www.tactnih.com](http://www.tactnih.com):**

- 5) 2006 Sterling Submission Application (You do **NOT** need to complete questions 29-39 of section C. This form is also available at <http://www.sterlingirb.com>).
- 6) Most recent Protocol Title and Signature Page (signed by the Site Investigator, available in the *Regulatory Requirements* section of the TACT website)

- 7) Completed **copy** of FDA Form 1572 (Please refer to the *Regulatory Requirements* section of the TACT website for instructions on how to fill out Form 1572). **Original FDA Form 1572 must be sent to the TACT CCC.**

**Fees for Applying to Sterling IRB**

**Each TACT clinical site is responsible for all IRB-related fees. The study is not responsible for paying IRB-related fees.**

**Accordingly, Sterling IRB will bill each clinical site individually. The site-specific fees for Sterling IRB are as follows:**

First year review (which includes site-specific submission of the documents listed above): \$300

Each subsequent year: \$300

Expedited review of a revision to the ICF: \$150

Any questions regarding submission of materials or payments should be directed to Emily Theriot, Senior Manager of Initial Review IRB administrator, at (888) 636-1062 or send an e-mail to [info@sterlingirb.com](mailto:info@sterlingirb.com).