



**Stroke Hyperglycemia Insulin Network Effort Trial**  
NIH-NINDS Sponsored Trial  
In collaboration with Neurological Emergencies Treatment Trials (NETT)  
Network

To: SHINE Study Teams  
From: SHINE Recruitment Leadership  
Date: January 21, 2016  
Re: Use of OmniTrace People Locating Service in SHINE

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Thank you for taking a moment to review this letter of instruction in regards to the SHINE clinical trial sponsored by the NIH-NINDS and the University of Virginia. As you may be aware, OmniTrace Corp. has been selected to assist in locating Lost to Follow-Up (LTFU) patients who have participated in the SHINE trial. OmniTrace specializes in LTFU searching and has assisted hundreds of studies since 2003.

This letter describes the process and transfer of information between the enrolling site and OmniTrace.

- 1) When a subject is at risk for being lost to follow up and contact information is not up to date, the clinical enrolling site will work with the SHINE Recruitment Leadership team to determine whether use of OmniTrace is indicated. Please note that OmniTrace can only be used at sites that have IRB approval and for subjects that have signed a consent form that includes details about the people locating service.
- 2) The University of Virginia has a business associate agreement with OmniTrace and will centrally pay for the cost of the service. The use of OmniTrace must be approved by the SHINE Recruitment Team for each subject and will be initiated by the University of Virginia.
- 3) Upon approval to use the service, the enrolling site will complete the attached Information Form. The form collects contact information from the enrolling site (Site name, Site number, contact person, phone, fax and email) as well as the patient's name, their last known address, last known phone and date of birth. Please note that OmniTrace does not access patient medical records and does not electronically store patient data. The enrolling site will directly fax the completed Information Form to OmniTrace.
- 4) Once OmniTrace has completed the search, they will fax a completed report containing all results to the enrolling site. For compliance reasons, OmniTrace does not make contact with any subjects of the search in order to verify results. As such, there will be occasions where their information may not be accurate. Please notify OmniTrace immediately if this is the case as they may have to run secondary searches. If they are not notified of incorrect results, they will consider them to be accurate. If OmniTrace determines the patient is deceased, they will provide the date of death and a source reference.