

How to Find Lost-to-Follow-up Subjects

By Kirk Rutherford and Norman M. Goldfarb

Beth, a study coordinator at a clinical research site, has been unable to contact her subject, Mark, for a month. She followed her site's SOP:

1. She attempted to contact him in a timely manner with a minimum of three phone calls.
2. She mailed a certified letter with return receipt requested expressing concern for Mark's well-being. The letter was not delivered.
3. After seven days, she mailed another certified letter with return-receipt-requested explaining his further obligations, such as returning unused study drug. The letter was returned with the stamp "ADDRESSEE MOVED. NO FORWARDING ADDRESS."
4. She documented all of the above activity.

Mark was now officially "lost-to-follow-up." He is not the first; the reality is that subjects disappear all the time.

The study sponsor then notified Beth of a potentially dangerous side effect of the study drug. It is essential for Mark to come in for special blood tests. What can Beth do to locate him?

Mark did not tell Beth not to contact him. Even if he had, she could still make the attempt because his health is at risk.

Unfortunately, Mark did not give Beth any emergency or alternate contact information. This circumstance probably qualifies as an emergency, so she could have used that information to find Mark. Unfortunately, the HIPAA authorization that Mark signed does not give Beth permission to contact Mark's landlord, relatives and friends who might know Mark's new address. Beth can only use third-party sources of information, such as those in Table 1.

In the future, Beth will include the following language in HIPAA authorizations:

If we lose contact with you during the study, we may attempt to find you through your emergency and alternate contacts or a professional service.

Beth spends a few hours attempting to locate Mark through the Internet, but without success. Mark moved too recently for his new information to show up in the databases, assuming it ever shows up. She considers using one of the services that advertise on the Internet to locate anyone for a small fee, but realizes that HIPAA regulations prohibit her from disclosing Mark's name to them without a contract including confidentiality restrictions. Such a contract would be impractical to obtain, especially with a company that has no experience locating lost to follow up patients. Furthermore, releasing Mark's name and contact information to such a service could expose him to identity theft, sale of his information, and illegal investigation tactics.

Beth informs the sponsor of her unsuccessful efforts to find Mark. The sponsor still wants her to find him, so it refers her to a company that specializes in such searches. The company's private investigator's license gives it access to databases available to law enforcement but not to the general public. These databases contain information such as credit, cell phone, unlisted telephone, federal, state and county records.

Mark's HIPAA authorization is written broadly enough to allow the sponsor to pass the information along to the search company, but the sponsor doesn't have time to get involved because all of its personnel are busy finalizing the study data.

The sponsor agrees to reimburse Beth's site for the search company's fee, which turns out to be less than she billed the sponsor for the time she has already spent attempting to locate Mark. Beth signs a contract with the search company and gives it Mark's name and obsolete contact information.

Does the search company find Mark? Heck, we don't know; Mark isn't a real person. But we can tell you that experienced lost-to-follow-up services, working in compliance with HIPAA regulations, are successful in over 85% of U.S. searches and over 70% of searches in other countries, including the third-world. U.S. searches typically take 3 to 15 business days, while international searches take 15 to 45 business days.

Table 1: Online Resources for Locating Lost-to-Follow-up Subjects

www.411.com	Directory assistance for the United States
www.whitepages.com	Directory assistance for the United States as well as reverse address and reverse phone searches
canada411.sympatico.ca	Directory assistance for Canada
www.aol.com/netfind/international.html	International directory assistance
www.publicdata.com	Drivers license and automobile ownership information available for some states; fee-based site
www.naco.org	Identify the county of any U.S. city, and then search county's website for any real estate, voter registration, and vital statistics records
www.ancestry.com	Information on people and their relatives; access to the Social Security Death Index
www.deathindexes.com	Death indexes for some states

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