



<b>105a Guidelines and Strategies for Maximizing Follow-up</b>	
Approved: TBIMS Project Directors	Effective Date: 4/1/2009
Attachments: None	Revised Date: Transferred to SOP template 09/16/08
Forms: <a href="#">Guidelines and Strategies for Maximizing Follow-up Form</a>	Reviewed Date: 12/12/2008
Review Committee	SOP committee

**Introduction:**

The TBI model systems have established best practices intended to maximize follow-up and suggest additional strategies that will help with locating those participants who are difficult to find and may eventually be considered lost to follow-up.

**Purpose:**

By outlining consistent steps that are to be performed for each TBIMS participant, the lost to follow-up rate should be lower thus maximizing follow-up.

**Scope:**

All TBIMS centers including the TBIMS longitudinal follow-up centers that conduct FORM II follow-ups.

**Responsibilities:**

The Guidelines and Strategies for Maximizing Follow-up should be used as the best practices for follow-up for the TBIMS.

**Procedural steps:**

- Attempt at follow-up should begin on the follow-up window open date.
- If the data collector cannot reach a subject after 2 weeks of attempted contact, the Best Practices methods 1-9 on the Guidelines and Strategies for Maximizing Follow-up Form are to be employed until the subject is reached or until the window closes.
- The Best Practices are the minimum expectations for methods that are to be employed to find and interview participants.
- These methods can be applied in any sequence to best fit the circumstances of each center.



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- The Guidelines and Strategies for Maximizing Follow-up Form must be completed and kept on file at the center for every participant that is entered into the National Database as lost to follow-up.
- The “Additional Strategies” on pages 4 & 5 of the Guidelines and Strategies for Maximizing Follow-up Form are recommended for each site to consider as it applies to them, but are not required.

## **Training requirements:**

Follow-up strategies will be discussed at the Data Collectors in-person conferences and is a possible topic for the quarterly data collectors teleconferences.

## **Compliance:**

All TBIMS centers and the TBIMS longitudinal follow-up centers are required to adhere to this procedure. The Guidelines and Strategies for Maximizing Follow-up Forms on all participants submitted to the TBIMS National Database as lost to follow-up as of 1/1/07 will be reviewed during the NDSC Quality Support Visits.

## **References:**

Never Say Lost: A Practical Guide for Maintaining Participant Follow-Up in Clinical Trials, 3<sup>rd</sup> edition. Pittsburgh, PA: National Surgical Adjuvant Breast and Bowel Project, Operations Center. Available as a pdf document at [http://www.nsabp.pitt.edu/Never\\_Say\\_Lost.htm](http://www.nsabp.pitt.edu/Never_Say_Lost.htm).

## **History:**

- 1) Version used to create this SOP = 04/01/06
- 2) Transferred to SOP template and approved by SOP Review Committee = 9/16/08
- 3) Added that follow-up should start when window opens. Review approved by Planning Committee and Project Directors 12/12/2008.

**Review schedule:** At least every 5 years.