



<b>105b GUIDELINES FOR COLLECTION OF FOLLOW-UP DATA</b>	
Approved: TBIMS Project Directors	Effective Date: 04/01/2009
Attachments: None	Revised Date: 10/1/2009
Forms: <a href="#">Guidelines and Strategies for Maximizing Follow-up</a>	Reviewed Date: 12/12/2008
Review Committee	SOP Committee

**Introduction:**

The TBIMS use an established set of rules including procedural steps for follow-up data collection (FORM II) for the TBIMS National Database.

**Purpose:**

To institute a standard course of action for data collection of the follow-up data for the NDB.

**Scope:**

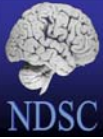
Current TBIMS and TBIMS longitudinal follow-up centers that are collecting follow-up data for the TBIMS National Database.

**Responsibilities:**

TBIMS staff responsible for Form II data collection for the TBIMS National Database (e.g., TBI researchers or clinicians, research assistants, study coordinators).

**Procedural steps:**

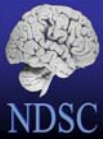
- For the first year of follow-up, data collection should occur within 2 months before to 2 months after the anniversary date of the injury. For follow-up year 2, data collection should occur within 3 months before to 3 months after the anniversary date of the injury. For follow-up years 5 and thereafter, data collection should occur within 6 months before to 6 months after the anniversary date of the injury.
- If a participant expires during initial inpatient rehabilitation, no Form II is to be completed.
- If a participant is still in their first inpatient rehabilitation stay at the time that their first anniversary of injury follow-up window is about to close, collect the Form II



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Year 1 follow-up information within the follow-up window. The rehabilitation hospital would be the residence, living with other patients, and to complete the FIM/DRS at that time.

- Follow-up should be attempted according to the TBIMS schedule for every participant (person with TBI) for whom a Form I was submitted, unless the participant was reported as expired or withdrew authorization to collect data in a prior follow-up year.
- If a participant withdraws authorization, that means that they do not wish to participate in any data collection from the time of withdrawal forward and will not be contacted again. It does not mean that all of their previously collected data is deleted from the database. Participants wishing to withdraw from the study should not be asked if they want all their previous data deleted from the database; however if they state they want all their previous data deleted then it should be deleted.
- A participant may refuse to be interviewed in a given year because they are too busy or do not wish to be bothered, etc. If this is the case, the interviewer should ask if he/she can contact the participant at the next follow-up window. If the participant agrees, then they are considered to have “refused” the current follow-up interview but not to have withdrawn authorization, and contact should be attempted at the next follow-up window.
- The primary source of information for the annual follow-up should be the participant. If the participant does not or cannot respond to certain questions or to all questions, then the significant other who knows the participant best becomes the participant’s proxy and may answer for the participant.
- A "significant other" is someone who knows the participant well and is available, able, and willing to answer questions reliably about that individual's daily life. This person is typically a family member, but is not required to be related to the participant or to live with that person. A significant other may be a non-traditional person such as a nurse at the facility where the person resides, a legal/public guardian, a roommate, etc. The significant other must know the participant sufficiently well to answer questions accurately. The significant other may qualify to answer some questions but not others.
- Questions that the proxy cannot answer reliably are coded as "unknown". The proxy must not answer V292g:SATISFACTION WITH LIFE and V280: PHQ-9.



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- When a person \*cannot be interviewed<sup>1</sup>, has expired, withdrawn authorization, refused to be interviewed, or is incarcerated, a limited amount of information--shown in the table below--is to be entered onto the Form II.

VARIABLE	LOST	EXPIRED	WITHDREW	INCARCERATED	REFUSED
	Attempt follow-up at next follow-up window opening.	No further follow-up.	No further follow-up.	Attempt follow-up at next follow-up window opening to determine if still incarcerated.	Attempt follow-up at next follow-up window opening.
200	Center ID Subject ID Follow-up year	Center ID Subject ID Follow-up year	Center ID Subject ID Follow-up year	Center ID Subject ID Follow-up year	Center ID Subject ID Follow-up year
20Aa(a,b)	999.99 (888.88 if known to be alive)	[ICD-9 code]	888.88	888.88	888.88
20Aa(c)	99999 (88888 if known to be alive)	[E code]	88888	88888	88888
20Ab	8	8	8	8	8
20Ac	8	8	8	8	8
20Ad	07	09	05	04	05
20Ae	88	88	88	88	88
201a	07/07/7777	06/06/6666	05/05/5555	07/07/7777	07/07/7777
201b	09/09/9999 (08/08/8888 if known to be alive)	[expiration date]	08/08/8888	08/08/8888	08/08/8888
209	blank	blank	blank	04	blank
all other variables	blank	blank	blank	blank	blank

<sup>1</sup> As specified in the Guidelines and Strategies for Maximizing Follow-up SOP.



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- **EXPIRED or WITHDREW AUTHORIZATION.** For participants who have expired or who withdrew authorization to continue with the study, enter the information shown in the table above. If the data collector learns prior to window opening that the person expired or withdraws authorization, the above information may be entered at any time up to and including the quarter in which the follow-up would have been due. Regardless of the quarter in which this information is entered, the “follow-up year” (last 2 digits of V200) is coded as the year of the follow-up that would have been due (e.g., year 01, year 02, year 05, etc). For expired participants and those who withdraw authorization, no additional Form II’s are ever entered.
- **INCARCERATED.** Data should not be collected from the participant or from a proxy while the participant is incarcerated. Find out if the incarcerated person will be released prior to the closing of the data collection window (only if obtaining such information is acceptable to your IRB and Investigator). If the person will be released before the window closes, then complete Form II data should be collected between the time of release and window closing. Do not collect follow-up information about participants who are incarcerated throughout the follow-up window. For these participants--and for participants who were released prior to window closing but about whom data was not able to be collected--enter the data shown in the table above. Persons who are on house arrest should be treated as incarcerated, however a person on parole or probation can be followed.
- Follow-up evaluations that have been started but not completed by the time the data collection window closes can be completed within two weeks after the window closes. Follow-up that were started or completed prior to the window start date should have a call back during the window to clarify that nothing has changed. The interview date would then be the date of the call back.
- Follow-up evaluations that have been started but cannot be completed within two weeks after the window closes should still be submitted to the National Database with missing data coded as unknown.
- Missing data may not be filled in using data obtained outside the follow-up window. Data collected outside the follow-up window may not be added to Form II’s that were originally entered without data. Data may be obtained outside the follow-up window from sources that had collected the data within the follow-up window--for example, data collected by clinicians during a clinical follow-up which occurred during the follow-up window.
- If phone contact with the participant is not possible, all information except V292g:SATISFACTION WITH LIFE and V280: PHQ-9 should be collected from a significant other by phone. The participant should be sent the



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V292g:SATISFACTION WITH LIFE and V280: PHQ-9 items by mail, along with a self-addressed return envelope if these questionnaires can be completed.

- If telephone contact with the participant and significant others is not successful, the participant should be sent the mailout version of the Form II after personalized information (name, enrollment date, name and contact information of Form II data collector) has been added to the form, along with a self-addressed return envelope.
- If adequate data are not obtained from the participant by telephone or by mailout, the mailout Form II should be sent to the significant other after personalized information (name, enrollment date, name and contact information of Form II data collector) has been added to the form, along with a self-addressed return envelope.

### **Training requirements:**

Staff who are responsible for the Form II data collection for TBIMS should be familiar with these criteria. On-going training will be conducted by quarterly data collector teleconferences and in-person data collectors meetings.

### **Compliance:**

All follow-up data collectors are required to comply with these guidelines, and attend the quarterly data collector teleconferences and in-person data collectors meetings.

### **References:**

None.

### **History:**

- 1) Version used to create this SOP = 04/01/08
- 2) Transferred to SOP template and approved by SOP Review Committee = 9/16/08
- 3) Revised to clarify difference between refused and withdrawn, and added PHQ-9 as variable not collected from proxy. Approved by Data Committee, SOP Committee, Planning Committee and Project Directors 12/12/2008.
- 4) Added clarification about not interviewing persons that are on house arrest. A person on parole or probation should be followed.
- 5) Added rule about interviewing subject prior to the window open date.

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