Registry One-Year Follow-Up Procedures

1. Introduction

Clinic staff are responsible for contacting all Registry participants or suitable informants approximately one year after the participant's qualifying date to determine the participant's vital status (if not known) and to learn of any hospitalizations that took place during the previous year. Procedures for one-year follow-up vary depending on whether or not the participant is known to be deceased and on whether or not he or she has been randomized into one of the SOLVD trials. These procedures are described in detail below; a flowchart summarizing them is presented in Figure 1.

2. Contact Procedures

2.1. Contact Log

A log documenting efforts to contact participants is given in Appendix I. This log may be modified to suit individual clinic operations, but should be designed to facilitate completing the RFF (especially Q 3.4 - Q 3.6 and Section D).

2.2. Registry Participants Not in SOLVD

If it is feasible, first contact the patient's private physician to determine vital status, if not known. The first contact attempt will be made by mail. Clinic staff will send a contact letter to the participant or, when the participant is known to be deceased, to the participant's next of kin or other informant. (See Section 3 for the contents of this letter.) It is recommended that "Address Correction Requested" be written or stamped on the envelope. The Coordinating Center plans to provide mail labels or software to facilitate these mailings. Appendix IIA shows samples of these letters.

Clinic staff should allow one month to receive a completed contact letter. If no response is received and the letter is not returned by the post office as undeliverable, the coordinator should attempt a telephone call. The contact form may be completed over the telephone. See Section 4 below for suggestions on locating hard to find participants if these attempts are not successful.

Once the contact form is received, it should be checked for completeness. Before the envelope is thrown away, check for any changes in address (to be recorded on the follow-up log). Also,



the date the informant completed the form can be estimated from the postmark date, if this has been left blank. The coordinator then completes the Registry Follow-Up Form (RFF) and, if necessary, Registry Hospitalization Forms (RHFs) and/or Registry Designation of Death Form (RDD). See Appendix III for a copy of the RFF and Section 5 for instructions.

It is likely that participants may not remember or record all hospitalizations experienced during the previous year. When reviewing medical records, coordinators should be on the lookout for additional hospitalizations. When additional hospitalizations are discovered, the response to Q4.2 of the RFF should be updated.

2.3. Registry Participants in SOLVD

Registry participants who have been randomized into one of the SOLVD trials are <u>not</u> contacted by mail for one-year follow-up. Instead, the coordinator should determine the participant's next scheduled SOLVD visit following the anniversary; the contact form and ladder of life questions are to be administered during the clinic visit. (Note that the ladder of life questionnaire need not be administered if the SOLVD Quality of Life questionnaire (SQL) is given at the visit. The ladder of life questions can be taken from the SQL.) The RFF and any RHFs or RDD, as needed, are then completed. Information from SHF or SFD forms may be used to complete the RHF and RDD.

Contact Letters

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A sample cover letter is given in Appendix I. The cover letter may be customized by the coordinator to increase rapport but the contact form should not be modified.

The contact packet should include (a) cover letter; (b) contact form with name, ID, beginning and ending dates of the follow-up period, and return dates filled in by the Coordinator; (c) ladder of life questionnaire as used in Registry substudy; and (d) release forms giving permission to review medical records at other hospitals. A stamped, self-addressed envelope will improve return rates.

4. Finding "Hard to Find" Participants

It is extremely important that all efforts be made to contact all Registry participants or a suitable informant. Besides needing complete data, the success of the study depends on there being no biases in the data. Since participants who are hard to locate are likely different from the remaining participants in socioeconomic and other health-related factors, their exclusion from the database will seriously affect the results. Likewise, a failure to obtain information about hospitalizations of deceased participants because, understandably, one does not want to "bother" the surviving spouse will result in a lack of documentation about an important subgroup. Obviously, these problems must be handled sensitively, but coordinators should always keep in mind that the success of the study is directly related to their vigilance in getting follow-up information.

The medical records or hospital billing department may have updated addresses and phone numbers of participants. Section D of the RBF contains the name, address and phone number of a friend or an acquaintance not living with the participant as well as the name and number of the participant's physician. It is suggested that in the interest of time these persons be contacted by telephone.

Other resources for U.S. clinics are described below. These resources may or may not be available in Canada or Belgium.

Social Security Administration: In the U.S., the local office of the Social Security Administration may be able to tell you if the participant has died or moved.

<u>Post Office</u>: In the United States, first-class mail will be forwarded to a new address, even one outside the country, for one year after the change-of-address form is submitted. The Post Office may have change-of-address cards on file after the date they have stopped forwarding the mail and may give you this information.

<u>Police Departments</u>: The local police department may be able to provide addresses for participants whose contact letters are returned as undeliverable by the Post Office.

<u>City Utility Companies</u>: Sometimes a local telephone or electrical company will tell you the address to which a resident's last bill was sent. They may also be able to tell you if the resident passed away (for example, if the last bill was sent to the next of kin).

<u>Polk Directories</u>: Community or university libraries or police departments will often have criss-cross directories (sometimes called "Polk directories" after the company that produces them). Polk directories are available for many towns and cities in the U.S. and Canada. These directories give the spouse's name, home telephone number, work telephone number, and employer. All of this information may be useful in locating a participant or addressing letters to spouses of deceased patients. In addition, the directories often have listings by street address. This will allow you to find the names and telephone numbers of the participant's neighbors, who may be able to tell you if the participant has died or moved. The Polk directories also list telephone numbers in numerical order, which will help you determine if the telephone is listed to the participant or to check for transposed numbers in the case where the number you have is incorrect. See sample pages of Polk directory in Appendix IIB.

State death registries and local or federal tax records are additional resources.

5. Registry Follow-up Form (RFF)

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A copy of the RFF is given in Appendix III. Specific instructions for completing this form are given below.

1.1. (Today's date): Self-explanatory.

1.2. (Initials of person completing form): Self-explanatory.

2.1-2.3. (Participant's name): Self-explanatory.

3.1. (Beginning date of follow-up period): Date of enrollment into the Registry (QUALDATE). See the SOLVD Registry Manual of operations for rules on determining the qualifying date of patients with more than one potential qualifying date.

3.2 (Ending date of follow-up period): For patients who are still alive after one year of the enrollment date, this date will be their one-year anniversary of enrollment; for those who have died this date will be the date of death.

3.3 (Date of contact): The date the contact form was completed by the participant or informant.

3.4 (Number of attempts before contact made): Enter here the number of mailings or telephone calls made to the participant or informant before contact was made. For the purpose of this question "attempted contact" is defined as use of a discrete source and/or method of reaching an informant which results in either contact or certain knowledge that the source or method is not useful. For example, three attempted telephone calls to the participant's home before the phone is answered is considered one attempted contact. A telephone call to the home, during which you learn that the participant has moved, and a call to the participant's employer for a forwarding address, constitute <u>two</u> attempted contacts.

3.5 (Form of contact): Circle code letter for the method of contact which successfully reached the participant or informant.

3.6 (Informant): Circle code letter for the person who completed the contact letter.

4.1 (Has participant been hospitalzed): Self-explanatory.

4.2 (Number of hospitalizations): Include hospitalizations listed on the contact letter as well as those discovered during review

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Contact Eval: Done RHF RDD	Name/ID	Qual Date	Prev. Known Dead?		visit Date	13	Contact (pe Sent	t ¶1 Rec		Contact Type Sent		#2 Rec	Type	Contact pe Sent	Rec	-+	Contact #4 Type Sent		Rec
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SOLVD REGISTRY CONTACT LOG FOR ONE-YEAR FOLLOW-UP

of medical records. This item should be updated as new hospitalizations are discovered. Note that a Registry Hospitalization Form should be completed for each hospitalization.

5. (Has participant died): Self-explanatory. Complete RDD and send death certificate with Registry cover sheet to the Coordinating Center. Exit the form.

6.1-6.3 (Ladder of Life): Enter "ladder of life" step numbers as indicated by the participant. Recall that for SOLVD patients these responses may be obtained from the Quality of Life questionnaire (Q. 35) if administered at the clinic visit.

7.1-7.6 (Has participant moved): Updating participant's address will help the three- and five-year follow-up procedures to be conducted by the Coordinating Center. Please enter new addresses when needed. Please enter the <u>complete</u> address even if only one part of the address has changed (i.e., a new street address in the same city).

 Registry Hospitalization Form (RHF) and Designation of Death (RDD) Forms

Follow the instructions for the SOLVD Hospitalization Form (SHF) and Final Designation of Death (SFD) form. Include HICDA codes only if given on hospital records.

9. Data Transmission and Time Windows

The RFF, RHF, and RDD are keyed in at the clinic and transmitted to the Coordinating Center on a weekly basis. A copy of the death certificate, with Registry Death Certificate Cover Sheet, is mailed to the Coordinating Center. Contact forms are kept on file at the clinic and are not sent to the Coordinating Center.

Ideally, contact with the participant and completion of the RFF should be made within 60 days of the participant's one-year anniversary of qualification. An additional interval of 21 days is given to enter and transmit the RFF before the form is considered late. RHF and RDD forms should be completed within 60 days of the clinic receiving the contact form; an additional 21 days are given for data entry and transmission.

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Appendix II Sample Cover Letter and Contact Forms

A. Registry participants not known to be deceased and not in SOLVD Trials

[On letterhead]

[Today's date]

[Name Address Registry ID Qualifying Date]

Re: SOLVD (Studies of Left Ventricular Dysfunction) Registry

Dear [Name]:

As you may recall, about a year ago when you visited [Registry hospital] in [city] we asked you if you would be willing to let us use information from your medical record for a study of people with either left ventricular dysfunction or heart failure. You graciously agreed to allow us to do this and agreed to let us contact you in a year to see how you are feeling.

That time has now come. Attached with this letter are two short questionnaires, one asking you about your health over the past year and the other asking you to tell us how you feel about your life. Could you please take a moment to answer these questions as completely as possible and return them to us soon as you can? It will likely take less than 10 minutes to fill out both forms. If you have any questions or if you'd rather complete this over the phone with me, you may call me at [number]. I may be calling you in a few weeks if I haven't heard from you otherwise. Please return the completed forms in the enclosed stamped self-addressed envelope.

You will notice that I have also enclosed a set of release forms. If you have been hospitalized anywhere other than [Registry hospital], please fill out a release form for <u>each</u> hospital.

Except in the unlikely event that we need to ask you something about your responses, completing these forms completes your role in the SOLVD Registry. We truly appreciate your help in our efforts to combat heart disease.

Sincerely,

Encl: Contact Form A Ladder of Life Release Forms Envelope

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	[On letterhead] SOLVD REGISTRY CONTACT FORM [For non-deceased participants; to be completed by participant or informant]
	CONDITION OF THE HEALTH OF Sam JONES
	Please complete the following questions and return to the address above:
	1. Today's date:
	2. Name of person completing form:
	3. Relationship to participant:
	4. Has the participant been hospitalized for any reason during the participant been hospitalized for any reason during the participant (1988) to
	5. If so, how many times?
	For each hospitalization, please list:
(NOTE: Please sign a release form for any hospital other than [mu flospital]. 6. Are there any other matters about the participant's health that ar concerning you at the present time?
-	Thank you very much for your time. Please complete the attached "Ladde Life" questionnaire and return all forms in the enclosed stamped self-addressed envelope by $[1/30/89]$.

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B. Next of Kin of Registry participant known to be deceased; Participant not in SOLVD Trials

[On letterhead]

[Today's date]

[Name] Address

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Re: Participant's Name Registry ID Qualifying Date]

Dear [Name]:

We are very sorry to learn of the death of [participant] during the past year. We know that this must be a sad time for you.

A year ago, [participant] agreed to participate to the Registry of the Studies of Left Ventricular Dysfunction (SOLVD Registry). [He/She] gave us permission to use information from [his/her] medical record in a study of patients with heart problems. As we explained to [participant], all information is used confidentially and solely for research purposes.

We know this may be painful for you, but could you please take a moment to complete the attached forms and send them to us in the enclosed stamped self-addressed envelope. It is something that [participant] would have done, if it were possible. A few minutes of your time will help us tackle the problem of heart disease for other patients. Please feel free to call me at [number] if you have any questions or would prefer to complete this over the telephone.

If [participant] was hospitalized anywhere in the past year other than [Registry Hospital], please fill out a release form for <u>each</u> hospital.

Again, we truly appreciate your help.

Sincerely,

Encl. Contact Form B Release Forms Envelope

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		SOLVD REGISTRY CONTACT FORM garding deceased participants]
	ORMATION REGARDING	Samuel Jones (Name) 0001
Ple:	ase complete the follo Today's date:	owing questions and return to the address above:
2.		ting form:
	Was the participant h	cipant: ospitalized <u>for any reason</u> during the period from the time of death?
	·	Yes No
5.	If so, how many times	?
	For each hospitalizat	ion, please list:
÷.,	Name of hospital	Approximate dates Reason(s) for hospitalization
	NOTE: Please sign a institution].	release form for <u>each</u> hospital other than [your

Thank you very much for your time. Please mail this form in the enclosed stamped self-addressed envelope by <u>Qan 30, 1989</u>.

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1201a Huggins Hardware Inc 967-6082

1203 Ashworth Charles W Jr & 942-545"

933-006-

1201 Talbert's Airport Road Gulf Service gas

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207 Bowles Keith @ 942-5551 211 Stevens Sandra 933-9583

60 Jones Alison 968-4654

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- 324 Rischbieter Michael 968-8640
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12/7/88	
REGISTRY ID: FORM	A: R F F VERSION: A VISIT: 0 2
INSTRUCTIONS: This form is to be completed on the basis of t phone interview. It should be completed with of enrollment. Consult the SOLVD Registry Ins Forms and Registry follow-up protocol for deta	in 60 days of the one-year anniversary
SOLVD REGISTRY FOLLOW-UP FORM (sc:	reen 1 of 3) (RFF page 1 of 2)
A. IDENTIFYING INFORMATION	B. CONTACT INFORMATION
1.1 Today's date:///	3.1 Follow-up period covers from (beginning date):
1.2 Initials of person completing form:	3.2 to (ending date):
	3.3 Date of contact (if in SOLVD, date of visit):
2.2 Participant's First Name:	Month Day Year
2.3 Participant's Middle Initial:	3.4 Number of attempts before contact successfully made:

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	Yes No Unknown
3.5 Form of successful contact (circle correct letter):	C. FOLLOW-UP DATA
Letter (L)	4.1 Has the participant been Y N U hospitalized?
Telephone (T)	(If NO or UNKNOWN, skip to Q. 5)
SOLVD Visit (S)	4.2 Number of hospitalizations:
Other (0)	(NOTE: Complete a Registry Hospitalization Form for EACH
No Contact Made (N)	hospitalization)
3.6 Informant (circle correct letter):	5. Has the participant died? Y N (If YES, complete a Registry Designation of Death form, send
Participant (P)	death certificate to Coordinating Center, & EXIT this form)
Relative/Spouse (R)	6. LADDER OF LIFE:
Friend/Acquaintance (F)	6.1 Ladder of Life step for
Employer (E)	PRESENT (01-10):
M.D./Nurse (M)	6.2 Ladder of Life step for
Other (0)	5 YEARS AGO (01-10):
None (N)	6.3 Ladder of Life step for
5	5 YEARS FROM NOW (01-10):
SOLVD REGISTRY FOLLOW-UP FORM	(screen 3 of 3) (RFF page 2 of 2)
D. UPDATING CONTACT INFORMATION Yes N	
7.1 Has the participant moved since the RBF Y N	7.4 State/Province:
(If NO, EXIT form) 7.2 Street Address:	7.5 Postal Code:
	7.6 Country:
7.3 City:	
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SOLVD REGISTRY FOLLOW-UP FORM (screen 2 of 3) (RFF page 2 of 2)

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