

QUALITY OF LIFE IN OAT INTERNATIONAL PROTOCOL

Quality of Life in OAT

Table of Contents

	<u>Page</u>
✧ QOL Contact Information	3
✧ Schedule of QOL Measurements and Data Collection	3
✧ QOL Protocol.	4
✧ QOL Protocol Flowsheet	5
✧ General Guidelines – Quality of Life	6
✧ Standard Interviewing Guidelines	7
✧ Baseline Questionnaire and Summary- Annotated	9
✧ Follow-Up General Instructions	17
✧ Follow-Up Questionnaire and Summary- Annotated	20
✧ QOL Baseline & Follow-Up Introductions	28
✧ QOL Scheduler	30
✧ Data Clarification Form.	31

QOL-OAT Contact Information

QUALITY OF LIFE (QOL) COORDINATING CENTER (DCRI- DUKE CLINICAL RESEARCH INSTITUTE, DURHAM, NC, USA)

Daniel Mark, MD, MPH	Principal Investigator	Phone: +1 (919) 668-8775 Fax: +1 (919) 668-7060 E-mail: mark0004@mc.duke.edu
Nancy Clapp-Channing, RN, MPH	Project Manager	Phone: +1 (919) 668-8717 Fax: +1 (919) 668-7054 E-mail: clapp001@mc.duke.edu
Tina Harding, RN	Project Coordinator	Phone: +1 (919) 668-8430 Fax: +1 (919) 668-7054 E-mail: hardi006@mc.duke.edu
Mailing Address: (Express Mail only)	Duke Clinical Research Institute 2400 Pratt Street Room 0311 Terrace Level Durham, NC 27705 USA	

Schedule of QOL - OAT Measurements and Data Collection

Baseline

- Complete Baseline QOL Questionnaire (beige) & Fax to DCRI at +1 (919) 668-7054
- Complete Baseline QOL Summary Page & Fax to DCRI at +1 (919) 668-7054

Follow-Up (4,12,24 months)

- Complete Follow-Up QOL Questionnaire (yellow) at 4, 12, and 24 months post randomization & Fax to DCRI at +1 (919) 668-7054
- Complete Follow-Up QOL Summary Page & Fax to DCRI at +1 (919) 668-7054

Protocol for QOL – OAT

3.16.1 Quality of Life and Health Status Data Collection *

QOL questionnaire data will be collected at baseline, four months, years one and two.

Content of the International Health-Related Quality of Life Questionnaire

The QOL questionnaire will include a battery of validated instruments that build on a generic core supplemented by more detailed and/or disease-specific measures where necessary to provide a comprehensive assessment of health-related quality of life. The major quality of life effects of the percutaneous revascularization in this trial are likely to manifest themselves as a change in what the patient can do (or feels capable of doing) physically, the level of somatic symptoms and level of psychological well-being. These domains will be assessed in detail. Other quality of life effects such as altered role functioning and social functioning would be expected to occur as a consequence of changes in the physical or psychological status. These domains will be assessed briefly.

The generic core instrument is the Medical Outcomes Study Short Form (SF36). The SF-36 is composed of nine scales which can be used separately or as a set; they include physical function, role function-physical, role function-emotional, general health, bodily pain, social function, psychological well-being/mental health, vitality, and health transitions. Each scale is scored separately and is transposed to a 0 to 100 scale.

Cardiac symptoms will be measured with the New York Heart Association (NYHA) congestive heart failure Class and the Canadian Cardiovascular Society Class for angina, which will be recorded on the clinical Study Report Form and collected during each follow-up telephone contact.

General psychological well being/mental health will be assessed using a five-item mental health scale from the SF-36. This measure has been shown to correlate well with clinically diagnosed anxiety and depression. General health perceptions will be assessed using the five-item scale from the SF-36 that includes a five-level ordinal ranking of the patient's overall health (excellent to poor). Scales from the SF-36 will be used to assess role functioning (both physical and emotional related limitations), bodily pain, social functioning and vitality.

As a global measure, patients will also be asked to rate their health on a 0-100 scale where 100 equals excellent health and 0 indicates a state of health equivalent to being dead. Although not strictly a utility measure, this rating scale assessment has been used to impute a time trade off value using a mathematical transformation developed by Torrance¹.

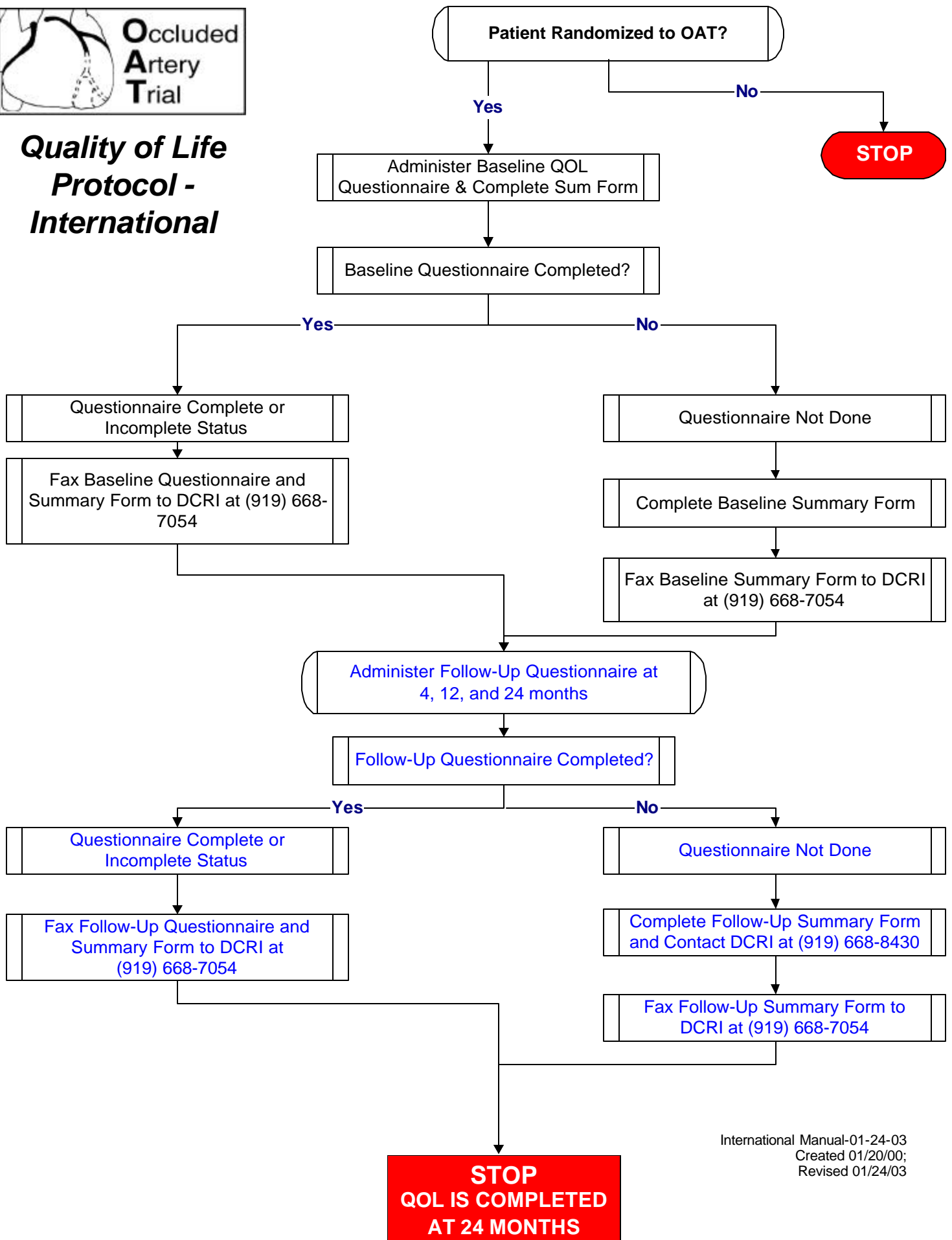
* Adapted from the OAT Protocol Version Date 11/1/00.

1. Torrance, GW. Utility approach to measuring health-quality of life. *J Chron Dis* 1987; 40: 595-600.

International Manual-01-24-03
Created 01/20/00;
Revised 01/24/03



Quality of Life Protocol - International



General Guidelines for QOL – OAT

Overview of Summary Forms and Questionnaire Data Collection

The following are some general guidelines for completion of the QOL Summary Forms and Questionnaires:

- A **Summary Form** **must** be completed for **every** patient randomized in OAT **whether or not a questionnaire is administered**.
- Please familiarize yourself with the “Standard Interviewing Guidelines” before administering QOL questionnaires.
- Please use **pen** and print neatly; **do not use pencil**.
- Please list all dates according to the QOL (European) date convention of day/month/year (**DD/MMM/YYYY**) ex. **25/JAN/2003**.
- Record the patient study # (hospital site # plus # assigned to the patient when enrolled in the trial) **on each page** of the questionnaire to avoid any misidentification of data.
- Record patient initials; please use **two** initials. It is very important to be consistent from form to form.
- **Corrections** are to be made by drawing a single line through the incorrect entry, then indicating the correct entry as near to the incorrect one as possible and initialing in small print and dating the correction; **Do not white out mistakes**. Example: ~~04/04/1999~~ 04/APR/2003TMH
- If data requested are not applicable to the patient, please code NA for Not Applicable. If data requested are not known by the patient, enter DK for Don't Know. If the patient refuses data requested, enter RF.
- The originals of each Summary Form and Questionnaire should be kept on file with the OAT clinical data forms.

Sending in the Forms

- **Baseline and Follow-Up Questionnaires and Summary Forms are to be faxed to the DCRI at +1 (919) 668-7054**. All originals should be kept on file with the Clinical Case Report Form at your institution.

OAT Baseline Questionnaire General Instructions And Summary Protocol

Baseline Instructions:

A Baseline Questionnaire should be **administered in person by the OAT Site Coordinator or his/her designate** following consent and during the patient's enrollment visit. By protocol, the baseline questionnaire should be completed **prior to the patient receiving any therapy**. If an extenuating circumstance prevents the questionnaire from being completed during the study enrollment visit, the questionnaire should be completed as close to the visit as possible, in person or by phone, and reason noted in the “Comments”. It is important that the questions be answered by the patient without input from friends or family. **[Please complete a Summary Form for every randomized patient.]**

- Record the patient's initials and study number assigned at the time of randomization; the **study number should be recorded on every page** of the questionnaire.
- The terms enrollment and randomization are used interchangeably. The randomization date refers to the date of the call to the Automatic Telephone Response System (ATRS). **Once a patient has received a study number, data must be collected.**
- The **OAT-QOL Questionnaire Introduction** (located on page 28) is written to assist the interviewer in the administration of the questionnaire.
- The questionnaire collects baseline information about the patient, measuring how he has been doing before his enrollment in OAT. It includes the eight subscales of the Medical Outcomes Study Short Form-36 and demographic information.

QOL - OAT Standard Interviewing Guidelines

The QOL OAT questionnaires must be administered in a standardized, structured interview format to eliminate as completely as possible any effect an interviewer might have on the patient's responses. The **questions should be asked *exactly as worded***, and the interviewers should not ask supplemental questions or make comments concerning the form. *It is important to read through the Annotated Questionnaires before administration.*

Role of the Interviewer in OAT:

1. Administer the questionnaire in a structured format.
2. Ensure that the patient understands the instructions and remains aware of them throughout the interview.
3. Allow the patient an opportunity to respond to each item.
4. Record the patient's responses completely and accurately.
5. To **eliminate bias** and to attempt to standardize the interview, the approach with the patient and guidelines (see "Administering the Questionnaire" box below) should be followed during the interview process. Before administering the questionnaire to a patient, practice the interview on family and friends.
6. Patients should respond to the items as they are written according to their own perception or interpretation of their meaning. Remember that the expression and tone of your voice will affect the patient's comfort level.

Your Interview Style With the Patient:

- Present yourself in a friendly and interested manner; however, **remain neutral**, relaxed and non-threatening.
- Give the patient the impression that you are basically interested in them, but are not personally involved with their response to the questionnaire.

Administering the Questionnaire:

- ◆ Read every item to the patient exactly as written.
- ◆ Read the items clearly and slowly.
- ◆ Pause briefly between the items so that the patient has enough time to respond.
- ◆ Concentrate on the items as you read them, that is, think about what each one is saying.
- ◆ Do not speed up your pace or develop a monotone toward the end of the interview.
- ◆ Remember that each patient is hearing the items for the first time.
- ◆ **Avoid making assumptions** about a patient's behavior and developing expectations about specific responses; assumptions could easily be incorrect, even though they may seem obvious.
- ◆ **Avoid the following potential biases:**
 - *Giving the impression that you approve or disapprove of any answer the patient gives*
 - *Acting surprised at any answers given*
 - *Showing special interest in hearing the answer to any specific question*

Guidelines for Approaching Six Possible Problem Situations:

1. Patient suggests that the wording of a statement be changed

Tell the patient that you will note his suggestion but right now he should only consider the statement as you have read it.

2. Patient refuses to answer a statement

Record patient refusal on questionnaire. Do not try to convince him to consider the statement.

3. Patient asks to read the statements himself

Explain that you have been instructed to read them to every patient, in order to keep all the interviews the same, even though it takes more time. Add that he may read along with you if he wishes and move to their side so that he can read them with you or offer him a blank set of statements.

4. Patient changes his/her response

You may make a correction anytime the patient requests it.

5. Patient complains that a statement or group of statements is too personal

Explain that often-personal aspects of our lives are affected by our health. Remind the patient that you are just a recorder and that all information he gives is completely confidential.

6. Patient discusses his/her illness, symptoms, or medical care

Do not encourage a conversation about the patient's health, instead just answer with a nod or smile or "um hum". If the patient continues, tell him that you really need to ask the questions right now, and you can talk after the interview is completed.

*-Adapted from Administration Procedures and Interviewing Training for the Sickness Impact Profile.
Joanne Conn, Ruth A. Bobbitt, Marilyn Bergner.
Dept. of Health Services, University of Washington, Seattle. July 1978: 3-20.*

OAT: Quality of Life

Annotated Baseline Summary and Questionnaire

***(Do not use the annotated or sample forms for patient administration;
use the forms provided by the QOL Coordinating Center.)***

QOL- OAT BASELINE SUMMARY PROTOCOL

A **Summary Form** must be completed for **every** patient randomized to QOL-OAT protocol.

Final Questionnaire Status

- Complete = 90% or more of questionnaire completed.
- Incomplete = at least 10% of questionnaire missing.
- Not Done = patient died, refused follow-up, or was unable to be located or contacted (and no proxy respondent could be located or contacted)

Note: If Incomplete or Not Done, the Reason must be coded.

Source of Information

- Enter the primary source of information for the questionnaire. *The patient, by protocol, should be the only source for the Baseline Questionnaire.*
-
-

Type of Administration

- In-person = administration by the Study Coordinator or designate at clinic or in the hospital.
-
-

Residence

- Enter place where the patient resides at the time of the interview. *If hospitalized, code Acute Care and Date of Admission.*
-
-

Comments

- Important text information regarding the patient or questionnaire should be added here.
-
-

Interviewer

- Enter initials of the person completing the Baseline questionnaire data.
-
-

QOL OAT Study

Baseline Questionnaire- Summary

Patient Study #: _____-_____-_____

Patient Initials: _____

Randomization Date: ____/____/____

FINAL QUESTIONNAIRE STATUS:

- ₁ Complete
- ₂ Incomplete → → → → → → → →
- ₃ Not Done → → → → → → → →

SOURCE OF INFORMATION:

- ₁ Patient
- ₂ Proxy
- ₃ Translator Interview
- ₄ Medical record

TYPE OF ADMINISTRATION:

- ₁ In person
- ₂ Phone
- ₃ Mail

RESIDENCE (of pt at time Summary Completed):

- ₁ Community / Outpatient Clinic
- ₂ Acute Care (in-pt hosp) → Admission Date: ____/____/____
- ₃ Nursing Home
- ₄ Rehab Institution

INTERVIEWER: _____

REASON FOR INCOMPLETE OR NOT DONE:

- ₁ Patient Died; Date of Death ____/____/____
- ₂ Patient too ill or deaf
- ₃ Patient unreliable
- ₄ Language barrier
- ₅ Situation not conducive for phone call
- ₆ Patient refused
- ₇ Other: Specify: _____

COMMENTS: _____

QOL OAT

Patient Study #: _____ - _____

International Baseline Quality of Life Questionnaire

Patient Initials: _____ - _____

The following questions are about your overall health and recent activities. Please check (✓) your choice for each question. The numbers beside each answer are there simply to help us record the information. Do not worry about them. Answer each question as best you can. This information is confidential and will not be released to anyone without your permission.

TODAY'S DATE: / /
 dd mmm yyyy

1. In general, would you say your health is:

- ₁ Excellent
- ₂ Very Good
- ₃ Good
- ₄ Fair
- ₅ Poor

Question 1: from the Medical Outcomes Study Short-Form 36 (SF-36); a measure of general health. Check one answer.

2. Compared to one year ago, how would you rate your health in general now?

- ₁ Much better now than one year ago
- ₂ Somewhat better now than one year ago
- ₃ About the same
- ₄ Somewhat worse now than one year ago
- ₅ Much worse now than one year ago

Question 2: from the Medical Outcomes Study Short-Form 36 (SF-36); a measure of current health compared to one year ago. Check one answer.

3. On a scale of 0 to 100, with 0 being equal to death and 100 being equal to excellent health, what number best describes your state of health in the past month? # _____

Question 3: a category rating scale that measures current overall health from death (0) to excellent health (100). If the patient expresses a range, first try to get an answer at one end or the other end of the range by saying, "Would you say, more like the low # or the high #? If that is not helpful, take the range and estimate the median overall health rating.

4. The following questions are about activities you might do during a typical day. Has your health limited you in these activities in the past month? If so, how much?

	No, Not Limited at All	Yes, Limited a Little	Yes, Limited a Lot
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
b. <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	1	2	3
c. Lifting or carrying groceries.	1	2	3
d. Climbing <u>several</u> flights of stairs.	1	2	3
e. Climbing <u>one</u> flight of stairs.	1	2	3
f. Bending, kneeling, or stooping.	1	2	3
g. Walking <u>more than a mile</u>	1	2	3
h. Walking <u>several blocks</u>	1	2	3
i. Walking <u>one block</u>	1	2	3
j. Bathing and dressing yourself.	1	2	3

Question 4: measures physical function as defined by the Short Form 36. It is a descending scale from highest to lowest function. Circle one answer for each section.

5. During the past month, have you had any of the following problems with your regular daily activities or work as a result of your physical health?

- | | Yes | No |
|---|---------------------------------------|---------------------------------------|
| a. Cut down on the <u>amount of time</u> you spent on work or other activities. | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| b. <u>Accomplished less</u> than you would like. | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| c. Were limited in the <u>kind</u> of work or other activities | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| d. Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort). | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |

Questions 5, 6, and 7:
 These questions, from the Medical Outcomes Study Short Form 36 (SF-36), comprise measures of role functioning and social functioning.

6. During the past month, have you had any of the following problems with your regular daily activities or work as a result of any emotional problems (such as feeling depressed or anxious)?

- | | Yes | No |
|--|---------------------------------------|---------------------------------------|
| a. Cut down on the <u>amount of time</u> you spent on work or other activities | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| b. <u>Accomplished less</u> work than you would like | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| c. Didn't do work or other activities as <u>carefully</u> as usual. | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |

7. During the past month, to what extent has your physical health or any emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- ₁ Not at all
- ₂ Slightly
- ₃ Moderately
- ₄ Quite a bit
- ₅ Extremely

8. How much bodily pain have you had during the past 4 weeks?

- ₁ None
- ₂ Very mild
- ₃ Mild
- ₄ Moderate
- ₅ Severe
- ₆ Very severe

Question 8:
 This question, from the Medical Outcomes Study Short Form 36 (SF-36), is a measure of bodily pain. Check one answer.

9. During the past 4 weeks, how much did pain interfere with your normal activities (including both work outside the home and house work)?

- ₁ Not at all
- ₂ A little bit
- ₃ Moderately
- ₄ Quite a bit
- ₅ Extremely

Question 9:
 This question, from the Medical Outcomes Study Short Form 36 (SF-36), is a measure of bodily pain. Check one answer.

10. These questions are about how you feel and how things have been with you during the past month. For each question, please indicate the one answer that comes closest to the way you have been feeling.

How much of the time during the past month . . .

	<u>All of the Time</u>	<u>Most of the Time</u>	<u>A Good Bit of the Time</u>	<u>Some of the Time</u>	<u>A Little of the Time</u>	<u>None of the Time</u>
a. did you feel full of pep?	1	2	3	4	5	6
b. have you been a very nervous person?	1	2	3	4	5	6
c. have you felt so down in the dumps nothing could cheer you up?	1	2	3	4	5	6
d. have you felt calm and peaceful?	1	2	3	4	5	6
e. did you have a lot of energy?	1	2	3	4	5	6
f. have you felt downhearted and blue?	1	2	3	4	5	6
g. did you feel worn out?	1	2	3	4	5	6
h. have you been a happy person?	1	2	3	4	5	6
i. did you feel tired?	1	2	3	4	5	6

Question 10 : These questions , from the Medical Outcomes Study Short Form 36 (SF-36), comprise measures of mental health status and vitality. Please ask the patient each question and circle one answer from the scale of 1-6.

11. During the past month, how much of the time has your physical health or any emotional problems limited your social activities (like visiting with friends, close relatives, etc.)?

- ₁ All of the time
- ₂ Most of the time
- ₃ Some of the time
- ₄ A little of the time
- ₅ None of the time

Question 11: This question, from the Medical Outcomes Study Short Form 36, measures the extent to which physical health or emotional problems interfere with normal social activities. Check one answer.

12. Please choose the answer that best describes how true or false each of the following statements is for you. (Circle one number on each line.)

	Definitely <u>True</u>	Mostly <u>True</u>	Not <u>Sure</u>	Mostly <u>False</u>	Definitely <u>False</u>
a. I seem to get sick a little easier than other people.	1	2	3	4	5
b. I am as healthy as anybody I know.	1	2	3	4	5
c. I expect my health to get worse.	1	2	3	4	5
d. My health is excellent.	1	2	3	4	5

Question 12: These questions are from the Medical Outcomes Study Short-Form 36 (SF-36). They are personal perceptions of health, including current health, health outlook, and resistance to illness. Have the patient rate each statement from the scale of 1-5.

The next set of questions is about you and your household.

13. What is the highest grade (# of years) you completed in school? (Circle one.)

- 0
- 1 2 3 4 5 6 7 8
- 9 10 11 12
- 13 14 15 16
- 17 18 19 20 21+

Question 13 asks for the last grade of education or year completed. For example, if someone attended but did not complete the 11th grade, enter "10".

- Any scenarios which are difficult to compute should be noted in the Comments section of the QOL Summary Form.
- The responses on this section vary depending on country.

14. Are you presently:

- ₁ Married or living as married
- ₂ Divorced
- ₃ Separated
- ₄ Widowed
- ₅ Never Married

Question 14 asks the patient's marital status. Separated generally means not living together. If not living together, but the patient considers himself/herself married (for example, the spouse is living in a nursing home), then code = married. Check one answer.

OAT: Quality of Life

Follow-Up General Instructions

***(Do not use the annotated or sample forms for patient administration;
use forms provided by the QOL Coordinating Center.)***

QOL-OAT Follow-Up General Instructions And Summary Protocol

A Follow-Up Questionnaire will be **interview administered by the OAT Site Coordinators**, or their designate at **4 month, 12 month and 24 month intervals**. It is important that the questions be asked of the patient. **Please complete a Summary Form for every randomized patient**. Collecting follow-up data is as critical as baseline collection. If a questionnaire cannot be done in person at one of the follow-up points, it should be **administered by telephone as close to the target date (intervals) as possible**. If the patient is too ill or unable to complete because of language problems, etc, a **Follow-Up Proxy Questionnaire** should be completed by a contact who can answer for the patient. (See *Proxy Instructions below*).

- If there are problems contacting a patient, please email, fax, or phone the QOL Coordinating Center (see page 3) to discuss the particulars; it is critical that we keep all patients in the study over the long-term.
- The questionnaire takes its content from the Baseline Questionnaire, but includes information in the month prior.
- Anchor the proper time frame in order to obtain valid information.

Follow-Up Protocol

- Every patient should be administered the Follow-Up Questionnaire at the clinic visit (or by phone if not returning to clinic) ideally with a two week window either side of the date that Follow-Up is due; if, because of extenuating circumstances the two week window cannot be met, the questionnaire should be completed within 6 weeks from when it was due. **A monthly telephone scheduler** will be sent of forms due (see *Sample of Scheduler attached on p.30*).
- *If no clinic follow-up and no phone contact* is made after five tries at different times of the day during one week, (OR if the phone has been disconnected or the number reassigned), try the following sources:
 - ❖ Hospital patient information (to check for rehospitalization)
 - ❖ Directory Information
 - ❖ Contacts listed on OAT patient information sheet
 - ❖ Emergency Contact/next of kin
 - ❖ Place of employment
 - ❖ Local Physician
 - ❖ Hospital medical record

Contacting Respondents (if telephone administration is necessary)

- You should **always** attempt to interview the patient first, regardless of who completed the previous questionnaire. When attempting to contact the patient you may discover the patient has died since the last interview or is in the hospital. If the patient has died, tactfully say you are sorry to learn of this death and code the date of death on the Summary Form. Do not attempt a Follow-Up Questionnaire.
- If the patient is currently in the hospital, you should determine from the household respondent when the patient is expected to be released. If the expected date of release is within a month after the due date, **postpone** the interview until the patient is discharged from the hospital rather than go to a proxy. If, however, the patient is not likely to be discharged within that time period or would in the estimation of the family member be too ill to complete the interview, **proceed with a proxy interview** as discussed below.
- If the patient is currently **residing** in a nursing home or rehabilitation center, determine from the household member or contact person if the patient could do the interview or the telephone from the facility. If the patient is unable to do the interview or does not have access to a telephone and is not expected to be released soon, proceed with a proxy interview as discussed below. If the patient could do the interview and has access to a telephone, get complete information on the name and location of the facility as well as the telephone number from the household member or contact person.
- If the patient does not have a **telephone**, determine from the contact person if the patient would be able to go to a telephone at a specified time for an interviewer to call him/her, for example, a neighbor's house. If the patient is not able to go to a phone, go to a proxy respondent as described below.
- In the rare instance that a patient is shielded by another household member, explain the importance of talking directly to the patient. If the patient agrees to allow the member to answer questions, administer a proxy interview.

Conducting Proxy Interviews

When attempting to interview a patient, you may find that the patient cannot be interviewed him/herself for one of the following reasons:

- ◆ The patient may be too **physically ill** to be administered questions.
- ◆ The patient may **not give reliable responses** or be too confused or disoriented to answer any questions.
- ◆ The patient may be **too hard of hearing** to be administered the interview over the telephone.
- ◆ The patient may be residing in a nursing home or other facility and not have **access to a telephone**.
- ◆ The patient may be a patient **in a hospital** and not be expected to be released in the contact period.
- ◆ The patient does not have a telephone and is not able to go to a **telephone** to be called.
- ◆ The patient may refuse to participate but be willing to give **permission for a proxy interview**.
- ◆ The patient may have **died** since the last contact.
- ◆ On the Follow-Up Summary Form, use proxy as source of information and be sure to indicate relationship of proxy to patient

Choosing a Proxy Respondent

- To be **eligible** to be a proxy respondent for a patient, the person must be 16 years of age or older, and knowledgeable about the patient's health.
- Select the person who knows the patient best. This will generally be a **family member** who lives with the patient such as a spouse. Another **household member**, the contact person, or a person who provides support if the patient lives alone may also be used. If the patient is residing in a long-term care facility, a **staff member** at the institution may serve as a proxy. It is important to interview someone who knows the patient well. If the patient has just been admitted to a facility, the staff member may not be knowledgeable about the hospitalizations prior to admission to the facility, employment history, or total number of outpatient visits since the last interview but may have very good information about current health. In some cases, a family member who plays an active role in the patient's care at the facility may be a good proxy respondent.
- You will in most cases be calling the patient's home first in an effort to interview the patient. If the family informs you that the patient is in a nursing home and unable to participate and that the family thinks a staff member at the facility would be the best proxy, ask the family to notify the facility, if possible, that a OAT Study representative will be calling.

Refusals and Lost to Follow-Up

- If a patient is **unable to be contacted** or is indeed lost and all sources of contact have been exhausted, or if a patient completely severs all relationship with OAT, fill out a Summary Form noting patient status (Alive, Unknown, etc.) and date of last attempted contact or date last known to be alive. [Because of "Intention to Treat Analysis", it is very important that patients do not withdraw their consent from the study.]
- **NOTE:** One explanation for **lack of compliance** with follow-up may be a patient's problem with a hospital bill or anger about his medical care. Listening and referring to an identified person in, e.g., the billing office may significantly improve his/her participation.

OAT: Quality of Life

Annotated Follow-Up Summary and Questionnaire

***(Do not use the annotated or sample forms for patient administration;
use Forms provided by the QOL Coordinating Center.)***

QOL - OAT FOLLOW-UP SUMMARY PROTOCOL

A Summary must be completed at 4 months, 1 year, and 2 years for every patient randomized to QOL OAT. (See *next page* for example)

Final Questionnaire Status

- Complete = 90% or more of questionnaire completed.
- Incomplete = at least 10% of questionnaire missing.
- Not Done = For example, patient died, or was unable to be located or contacted (and no proxy respondent could be located or contacted)

Note: If Incomplete or Not Done, the Reason must be coded.

Source of Information

- Enter the primary source of information for the questionnaire. The patient, by protocol, should be administered the Follow-Up Questionnaire.
 - In specified instances, if a patient has died or is too ill to complete the questionnaire, a proxy respondent is indicated.
 - Medical record is only indicated if used to determine an alive/dead Follow-Up Status and or to assist in proxy completion.
-
-

Type of Administration

- In-person = administration by the Study Coordinator or designate at clinic or in the hospital.
 - Phone is indicated if patient does not return to clinic or, if circumstances prevent questionnaire completion in-person.
 - Mail is indicated only if phone or in person interview is impossible.
-
-

Follow-Up Status if UTL/UTC

- This should be completed only if the patient cannot be located or contacted by any means. Date is last date known to be alive, e.g., if patient was know to have been to clinic or rehospitalized or was sighted by someone who does not know patient well enough to be proxy respondent.
-
-

Interviewer

- Enter initials of person administering the Follow-Up Questionnaire.
-
-

Residence

- Enter place where the patient physically resides at the time of the interview. If the patient dies during follow-up, enter where s/he died (e.g. community/at home, acute care/hospital, etc.)
-
-

Comments

- Important text information regarding the patient or questionnaire should be added here.

International Manual-01-24-03
Created 01/20/00;
Revised 01/24/03

QOL OAT Study
Follow-Up Summary

Patient Study #: _____ - _____

Patient Initials: _____

Follow-Up Interval: 4mo. 12mo. 24mo.

FINAL QUESTIONNAIRE STATUS:

- ₁ Complete
- ₂ Incomplete → → → → → → → →
- ₃ Not Done → → → → → → → →

SOURCE OF INFORMATION:

- ₁ Patient
- ₂ Proxy
- ₃ Translator Interview
- ₄ Medical record

TYPE OF ADMINISTRATION:

- ₁ In person
- ₂ Phone
- ₃ Mail

RESIDENCE (of pt at time Summary Completed):

- ₁ Community / Outpatient Clinic
- ₂ Acute Care (in-pt hosp)
- ₃ Nursing Home
- ₄ Rehab Institution

REASON FOR INCOMPLETE OR NOT DONE:

- ₁ Patient Died; Date of Death ___/___/___
- ₂ Patient too ill or deaf
- ₃ Patient unreliable
- ₄ Language barrier
- ₅ Situation not conducive for phone call
- ₆ Patient refused
- ₇ Other: Specify: _____
- ₈ Unable to Locate/Contact patient (UTL/UTC)

FOLLOW-UP STATUS IF UTL/UTC:

- ₁ Alive → Date Last Contact Alive ___/___/___
- ₂ Unknown → Date Last Contact Alive ___/___/___

COMMENTS: _____

INTERVIEWER: _____

QOL OAT

Patient Study #: _____ - _____

International Follow-Up Quality of Life Questionnaire

Patient Initials: _____ - _____

The following questions are about your overall health and recent activities. Please check (✓) your choice for each question. The numbers beside each answer are there simply to help us record the information. Do not worry about them. Answer each question as best you can. This information is confidential and will not be released to anyone without your permission.

TODAY'S DATE: / /
 dd mmm yyyy

1. In general, would you say your health is:

- ₁ Excellent
- ₂ Very Good
- ₃ Good
- ₄ Fair
- ₅ Poor

2. Compared to one year ago, how would you rate your health in general now?

- ₁ Much better now than one year ago
- ₂ Somewhat better now than one year ago
- ₃ About the same
- ₄ Somewhat worse now than one year ago
- ₅ Much worse now than one year ago

3. On a scale of 0 to 100, with 0 being equal to death and 100 being equal to excellent health, what number best describes your state of health in the past month? # _____

4. The following questions are about activities you might do during a typical day. Has your health limited you in these activities in the past month? If so, how much?

	No, Not Limited <u>at All</u>	Yes, Limited a <u>Little</u>	Yes, Limited a <u>Lot</u>
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
b. <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	1	2	3
c. Lifting or carrying groceries.	1	2	3
d. Climbing <u>several</u> flights of stairs.	1	2	3
e. Climbing <u>one</u> flight of stairs.	1	2	3
f. Bending, kneeling, or stooping.	1	2	3
g. Walking <u>more than a mile</u>	1	2	3
h. Walking <u>several blocks</u>	1	2	3
i. Walking <u>one block</u>	1	2	3
j. Bathing and dressing yourself.	1	2	3

5. During the past month, have you had any of the following problems with your regular daily activities or work as a result of your physical health?

- | | Yes | No |
|---|---------------------------------------|---------------------------------------|
| a. Cut down on the <u>amount of time</u> you spent on work or other activities. | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| b. <u>Accomplished less</u> than you would like. | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| c. Were limited in the <u>kind</u> of work or other activities | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| d. Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort). | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |

6. During the past month, have you had any of the following problems with your regular daily activities or work as a result of any emotional problems (such as feeling depressed or anxious)?

- | | Yes | No |
|--|---------------------------------------|---------------------------------------|
| a. Cut down on the <u>amount of time</u> you spent on work or other activities | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| b. <u>Accomplished less</u> work than you would like | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |
| c. Didn't do work or other activities as <u>carefully</u> as usual. | <input type="checkbox"/> ₁ | <input type="checkbox"/> ₂ |

7. During the past month, to what extent has your physical health or any emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- ₁ Not at all
- ₂ Slightly
- ₃ Moderately
- ₄ Quite a bit
- ₅ Extremely

8. How much bodily pain have you had during the past 4 weeks?

- ₁ None
- ₂ Very mild
- ₃ Mild
- ₄ Moderate

9. During the past 4 weeks, how much did pain interfere with your normal activities (including both work outside the home and housework)?

- ₁ Not at all
- ₂ A little bit ?
- ₃ Moderately
- ₄ Quite a bit
- ₅ Extremely

10. These questions are about how you feel and how things have been with you during the past month. For each question, please indicate the one answer that comes closest to the way you have been feeling.

How much of the time during the past month . . .

	<u>All of the Time</u>	<u>Most of the Time</u>	<u>A Good Bit of the Time</u>	<u>Some of the Time</u>	<u>A Little of the Time</u>	<u>None of the Time</u>
a. did you feel full of pep?	1	2	3	4	5	6
b. have you been a very nervous person?	1	2	3	4	5	6
c. have you felt so down in the dumps nothing could cheer you up?	1	2	3	4	5	6
d. have you felt calm and peaceful?	1	2	3	4	5	6
e. did you have a lot of energy?	1	2	3	4	5	6
f. have you felt downhearted and blue?	1	2	3	4	5	6
g. did you feel worn out?	1	2	3	4	5	6
h. have you been a happy person?	1	2	3	4	5	6
i. did you feel tired?	1	2	3	4	5	6

11. During the past month, how much of the time has your physical health or any emotional problems limited your social activities (like visiting with friends, close relatives, etc.)?

- ₁ All of the time
- ₂ Most of the time
- ₃ Some of the time
- ₄ A little of the time
- ₅ None of the time

12. Please choose the answer that best describes how true or false each of the following statements is for you. (*Circle one number on each line.*)

	<u>Definitely True</u>	<u>Mostly True</u>	<u>Not Sure</u>	<u>Mostly False</u>	<u>Definitely False</u>
a. I seem to get sick a little easier than other people.	1	2	3	4	5
b. I am as healthy as anybody I know.	1	2	3	4	5
c. I expect my health to get worse.	1	2	3	4	5
d. My health is excellent.	1	2	3	4	5

OAT -QOL Questionnaire Introduction

I am working for the OAT study that you were enrolled in.

As part of the study, I would like to ask you some questions about how you were doing before your heart attack and how your health has been. The purpose of these questions is to help us understand better the effects of our medical treatments on the quality of patients' lives.

Your participation in this study is voluntary, and let me assure you that everything you say is confidential and will not be released to anyone without your permission. I will answer any questions you may have as we go along. If there are any questions you do not wish to answer, please tell me and we can skip them.

I would like to talk to you now if possible. The questions will take about 20 minutes.
(PAUSE)

DO NOT DUPLICATE WITHOUT PERMISSION OF THE DUKE QOL RESEARCH GROUP

OAT -QOL Follow-Up Questionnaire Introduction

I am working for the OAT study that you are participating in. You answered some questions for me last (DATE OF LAST QOL CONTACT) and I am calling back to see how you are doing now.

Just to remind you, the purpose of these questions is to help us understand better the how our medical treatments affect the quality of our patients' lives.

Your participation in this study is voluntary, and let me assure you that everything you say is confidential and will not be released to anyone without your permission. I will answer any questions you may have as we go along. If there are any questions you do not wish to answer, please tell me and we can skip them.

I would like to talk to you now if possible. The questions will take about 20 minutes.
(PAUSE)

DO NOT DUPLICATE WITHOUT PERMISSION OF THE DUKE QOL RESEARCH GROUP

EXAMPLE OF THE MONTHLY QOL OAT FORMS SCHEDULER

QOL OAT FORMS and BILLS SCHEDULER

Tuesday, January 30, 2003

Site No.: 000
Site Name: University Health Care

Attention: **Study Coordinator**
Fax: (999) 999-9999
Phone: (999) 999-9999

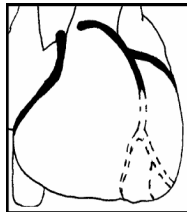
University Health Care
5555 Ridge Avenue
Box 555
Somewhere, NC USA 55555

QOL Summary/Questionnaires
Fax to: DCRI
(919) 668-7054

Study No.	Date of Randomization	Pt Init	Item	Description	Due Date	Note
000-002	01/22/2003	WS	QOL	Baseline QOL Summary/Questionnaire	01/22/2003	Due
000-003	01/25/2003	AM	QOL	4 month QOL Summary/Questionnaire	04/25/2003	Due

! REMINDER: Fax Data Entry forms are no longer used. Please fax only the Summary form and Questionnaire to DCRI.

If you have any questions or concerns contact Tina Harding at (919) 668-8430 or Fax at (919) 668-7054.



**Occluded
Artery
Trial**

DATA CLARIFICATION SAMPLE FORM
QOL OAT
January 24, 2003

Site No: #000
Attention: Site Coordinator
Phone: 999-999-9999
Fax: 999-999-9999

Site Name
Address Line 1
Address Line 2
City, ST
Country, ZIP

The following are routine queries for missing or unclear data on the OAT Quality of Life Questionnaires. Please clarify the data in the "Corrected Data" column for each query. Please date and initial all changes on the questionnaires retained at your site.

<i>Pt #</i>	<i>Init</i>	<i>Form</i>	<i>Missing Data</i>	<i>Corrected Data</i>
000-001	IF	Summary	Acute Care Admit Date	
000-001	IF	Baseline	37. Marital Status:	
000-002	MM	Summary	Residence	
000-002	MM	4 month	Date of Questionnaire	

Please sign and date this form and **fax** it back ASAP to Tina Harding at **(919) 668-7054**. If you have any questions or concerns, please call Tina Harding at (919) 668-8430.

Site Coordinator Signature

Date