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# EQOL OAT

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## Table of Contents

	<u>Page</u>
❖ Schedule of EQOL Measurements and Data Collection . . . .	3
❖ QOL Protocol Flowsheet . . . . .	5
❖ General Guidelines – Quality of Life . . . . .	7
❖ Standard Interviewing Guidelines . . . . .	9
❖ Baseline Questionnaire and Summary- Annotated . . . . .	11
❖ Follow-Up and Proxy General Instructions . . . . .	34
❖ Follow-Up Questionnaire and Summary- Annotated . . . . .	37
❖ Proxy Questionnaire (sample) . . . . .	51
❖ QOL Baseline & Follow-Up Introductions . . . . .	55
❖ EQOL Magnet Information . . . . .	57
❖ EQOL Scheduler . . . . .	59
❖ Data Clarification Form. . . . .	60
❖ Economic Data Collection . . . . .	61
❖ Baseline Questionnaire and Summary Form . . . . .	<i>Gray pages</i>
❖ Follow-Up Questionnaire and Summary Form . . . . .	<i>Yellow pages</i>
❖ Proxy Questionnaire . . . . .	<i>Blue pages</i>



# **Schedule of EQOL - OAT Measurements and Data Collection**

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## ***Baseline***

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- Complete Baseline QOL Questionnaire (Gray) & Fax to DCRI at (919) 668-7054
- Complete Baseline QOL Summary Page & Fax to DCRI at (919) 668-7054
- Fax signed Patient Consent Form to DCRI at (919) 668-7054

## ***Follow-Up (4,12,24 months)***

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- Complete Follow-Up QOL Questionnaire at 4, 12, and 24 month follow-ups (Yellow) & Fax to DCRI at (919) 668-7054
- Complete Follow-Up QOL Summary Page & Fax to DCRI at (919) 668-7054

## ***Rehospitalization***

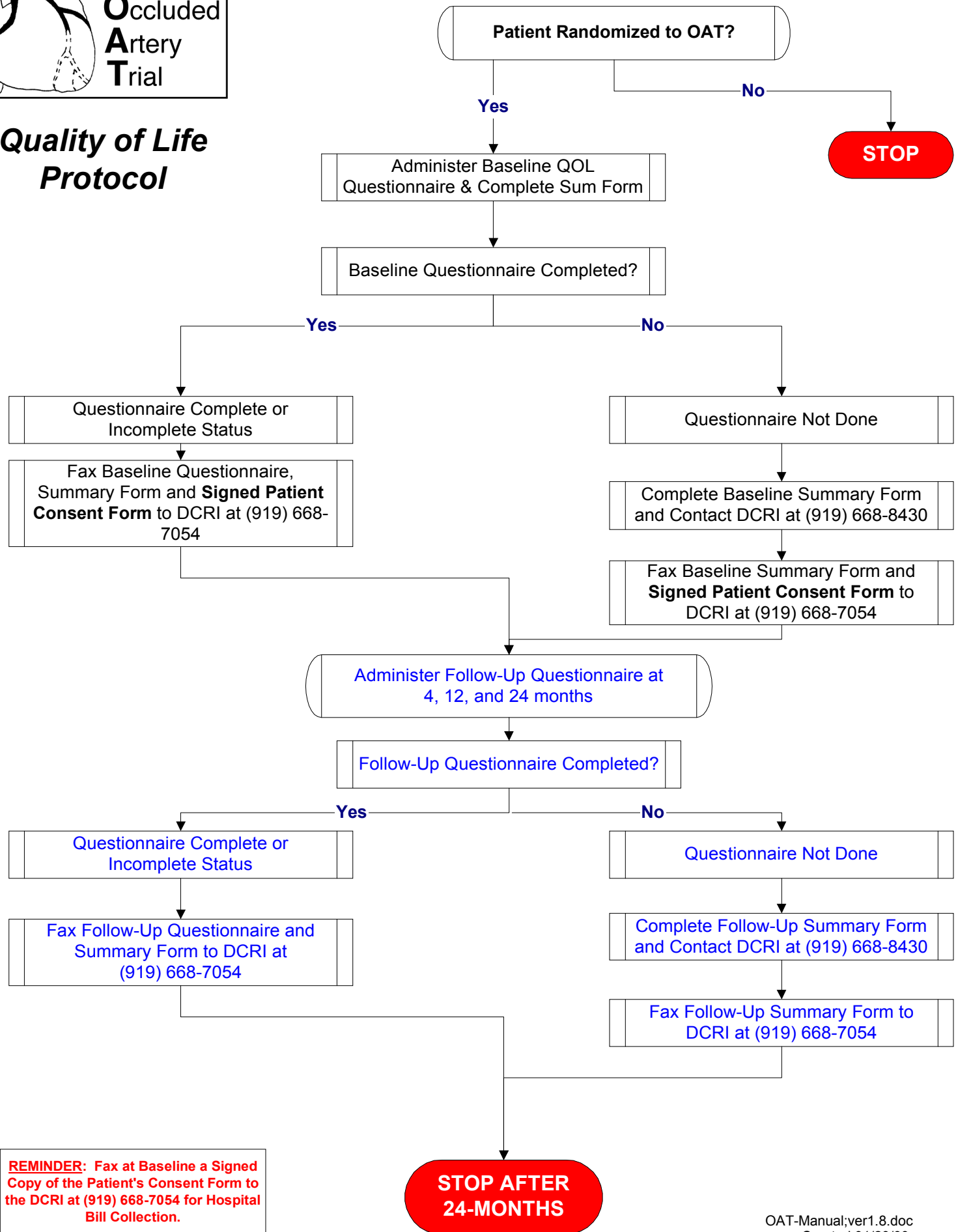
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- Follow Forms 11 and 15 Instructions





## Quality of Life Protocol



**REMINDER:** Fax at Baseline a Signed Copy of the Patient's Consent Form to the DCRI at (919) 668-7054 for Hospital Bill Collection.



# **General Guidelines for EQOL – OAT**

## **Overview of Summary Forms and Questionnaire Data Collection**

The following are some general guidelines for completion of the EQOL 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 EQOL questionnaires.
- Please use **pen** and print neatly; **do not use pencil**.
- Please list all dates as month/day/year (MMM/DD/YYYY), ex. **JAN/25/2000**
- 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~~ APR/04/2000 *TMH*
- 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.
- A **telephoned retest of the questionnaire** will be completed between 12 and 24 months on a total of 100 randomly selected patients by a representative of the EQOL-OAT Coordinating Center. These will serve as measures of reliability and of standardization of the interview. No identifying names will be included on the questionnaires or database.

### ***Sending in the Forms:***

- **Baseline and Follow-Up Questionnaires and Summary Forms are to be faxed to the DCRI at (919) 668-7054.** All originals should be kept on file with the Clinical Case Report Form at your institution.
- **USA Only: Patient Consent Forms (signed) need to be faxed to the DCRI with the Baseline Questionnaires.** Please make sure the patient's name is printed legibly.

## **OAT Base 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-EQOL Questionnaire Introduction** (located on page 51) is written to assist the interviewer in the administration of the questionnaire. Ask the patient to assist you in completing the questionnaire by using the **OAT-EQOL Magnet** (see page 53 for Magnet Protocol).
- The questionnaire collects baseline information about the patient, measuring how he has been doing before his enrollment in OAT. The data form has several major sections: general health rating and disability days, physical function, employment, Rand SF-36, utility time trade-off, category rating of health, demographic and household information.





# EQOL - OAT Standard Interviewing Guidelines

The EQOL 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. Ideally, all interviews in the study should be so standard that the only variability is in patient behavior from one time to another. Therefore, 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 DCRI EQOL group.)***

# **EQOL- OAT BASELINE SUMMARY PROTOCOL**

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

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## **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.***

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## **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.
- 

## **Job Class- Do Not Code**

- Job classifications will be coded by the EQOL Research Group.
- 
-

**EQOL 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

**Do Not Complete Below This Line: Duke EQOL Use Only**

**JOB CLASS:**

- 1 Exec/Managerial
- 2 Tech/Sales/Clerical
- 3 Service
- 4 Farm/Forestry
- 5 Prod/Prec/Repair
- 6 Operator/Laborer
- DK

# EQOL - OAT BASELINE QUESTIONNAIRE PROTOCOL

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**This questionnaire should be administered by the site coordinator or designate following consent and prior to therapy unless there are extenuating circumstances.**

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**Today's Date:** This is the **date** the **questionnaire** is **administered**.

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## **Questions 1-2, (Short Form-36)**

These questions, originally from the Medical Outcomes Study, comprise measures of general health, and have been used in other EQOL Outcomes studies.

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## **Question 3**

This question asks for a subjective rating of the patient's health. If a patient states he/she "can't" do much of anything, but also doesn't want to do much, the **response** should be coded, not the qualifier.

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## **Question 4 –5**

These questions are an estimate of the **total number** of reduced activity days in bed (while at **home, nursing home, etc.**) due to **illness, injury, or any health reason** in the past six weeks.

- Do not include days when patient was **hospitalized**; this measures bed days at **home/nursing home, etc. only**
- "All or most of the day" is at least  $\frac{3}{4}$  of the daylight hours.
- "Bed" = anything used for sleeping (i.e. recliner, sofa, cot, mattress, etc.)  
**Ex.** If patient was on the sofa all day watching television because s/he was too ill to get around, s/he would be in bed.
- **The sum of these 2 questions cannot exceed 42 (6 weeks x 7 days).**

**Question 5** determines how many days, **other than those spent in bed (while at home, nursing home, etc.)** reported in Question 4, that the patient had to cut down on his/her usual activities because of **any health reason OR doctor's or nurse's orders**.

- "Usual" activities = whatever is/was usual for the particular patient (either work or "at home" activities)  
**Ex:** A patient may have had to work fewer hours, miss work all day, not lift or carry certain materials, restrict standing or walking, etc.
  - **any** "cut down" the patient perceives is acceptable.
  - **Total number of days in Questions 4 and 5 cannot be greater than 42.**
-

# EQOL OAT

Patient Study #: \_\_\_\_\_-\_\_\_\_\_

## Baseline Quality of Life Questionnaire

Patient Initials: \_\_\_\_\_-\_\_\_\_\_

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*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: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

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

- <sub>1</sub> Excellent
- <sub>2</sub> Very Good
- <sub>3</sub> Good
- <sub>4</sub> Fair
- <sub>5</sub> Poor

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

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

**3. Which of the following statements describes the way you were in the month before your hospitalization?**

- <sub>1</sub> My health allowed me to do anything I wanted to do.
- <sub>2</sub> My health allowed me to do almost anything I wanted to do.
- <sub>3</sub> I had trouble doing some ordinary activities.
- <sub>4</sub> I had trouble doing almost anything.

**4. In the past six weeks, about how many days did you stay in bed (while at home) for all or most of the day because of your health? # \_\_\_\_\_**

**5. Not counting the days you had to stay in bed, in the past six weeks, about how many days did you have to cut down on your usual activities because of your health? # \_\_\_\_\_**

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## Questions 6-17

These items comprise the Duke Activity Status Index (DASI) which measures the physical **ability to perform** certain activities **in the past month**, as opposed to not being able to do them or not having the opportunity to do them. They measure what the patient has been **able to do** (i.e. his/her **proven performance or equivalent**). The 12 items cover a spectrum of difficulty and several dimensions of normal life. **[If the patient has a sudden deterioration in function just prior to his/her OAT enrollment, then his/her response should reflect what s/he could do in the time just before the deterioration.]**

- The intent is to determine if the patient can do the activities without difficulty, allowing the **respondent** to define “difficulty”.
- Questions 9-17 determine if s/he can do **any** of the listed activities without difficulty. The response of **the activity s/he can do best** should be coded.
  - ◆ **Example 1:** Suppose a patient does not do housework (“light or moderate”) because someone else does it. If he/she can **currently** do activities of **comparable** difficulty and therefore **knows s/he could** physically do housework with no difficulty or with some difficulty, then his or her answer should be coded as such.
  - ◆ **Example 2:** Suppose a patient has not participated in any sports in several years and is now fairly sedentary. Since s/he has not done an activity of that difficulty prior to enrollment and he/she knows that he/she could not do it, his/her answer should be coded **No**.
  - ◆ **Example 3:** Suppose a patient has had a stroke and cannot do some activities. His/her response should be coded “**NO**” to things s/he cannot do, **regardless** of the physical impairment.
- Any response “**Yes, but...**”= “**Yes, but with some difficulty.**”
- Question 15 in regards to sexual relations: if the patient is Widow/Widower/No Partner, etc., code as **NA**.
- A patient not doing activities because of **doctor’s orders = NA**.
- Similarly, a patient who **does not know** if s/he can do an activity and doesn’t know if s/he could OR doesn’t have an equivalent activity, should be coded as “**NA**”.
- **IMPORTANT: One response must be coded for each question.**  
***If a patient refuses to respond, then write in RF.***



*The next set of questions are about any physical limitations you might have had in the month before your hospitalization. For each question, please rate whether you are physically able to do one or more of the activities without difficulty, with some difficulty, you couldn't do it, or you don't do it for other reasons (NA).*

	<u>Yes, with no difficulty</u>	<u>Yes, but with some difficulty</u>	<u>No, I couldn't do this</u>	<u>NA</u>
<b>Could you. . .</b>				
6. take care of yourself, that is, eating, dressing, bathing, and using the toilet? . . . . .	1	2	3	7
7. walk indoors, such as around your house? . . . . .	1	2	3	7
8. walk a block or two on level ground? . . . . .	1	2	3	7

*For some of the following activity questions, there will be more than one activity mentioned like climb a flight of stairs or walk up a hill. Answer each question according to the one activity you can do best.*

	<u>Yes, with no difficulty</u>	<u>Yes, but with some difficulty</u>	<u>No, I couldn't do this</u>	<u>NA</u>
<b>Could you. . .</b>				
9. climb a flight of stairs or walk up a hill? . . . . .	1	2	3	7
10. run a short distance? . . . . .	1	2	3	7
11. do light work around the house like dusting or washing dishes? . . . . .	1	2	3	7
12. do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries? . . . . .	1	2	3	7
13. do heavy work around the house like scrubbing floors or lifting or moving heavy furniture? . . . . .	1	2	3	7
14. do yard work like raking leaves, weeding, or pushing a power mower? . . . . .	1	2	3	7
15. have sexual relations? . . . . .	1	2	3	7
16. participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football? . . . . .	1	2	3	7
17. participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing? . . . . .	1	2	3	7

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### **Questions 18 and 19 (Short Form-36)**

These questions, originally from the Medical Outcomes Study, comprise measures of bodily pain.

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### **Question 20A-20E**

These questions comprise the Rose Angina Questionnaire. It is very important to read the complete definition so the patient can accurately respond whether angina has been experienced in the past month. Do not probe as you would clinically.

**Question 20A:** If patient states they have had angina continuously for an entire day: code as **7** times; if two days then **14** times, if 3 days or more then **20** times.

---

**18. How much bodily pain have you had during the past month?**

- <sub>1</sub> None
- <sub>2</sub> Very mild
- <sub>3</sub> Mild
- <sub>4</sub> Moderate
- <sub>5</sub> Severe
- <sub>6</sub> Very severe

**19. During the past month, how much did pain interfere with your normal work (including both work outside the home and housework)?**

- <sub>1</sub> Not at all
- <sub>2</sub> A little bit   ▶▶▶▶▶▶
- <sub>3</sub> Moderately   ▶▶▶▶▶▶
- <sub>4</sub> Quite a bit   ▶▶▶▶▶▶
- <sub>5</sub> Extremely   ▶▶▶▶▶▶

**What kind of pain was this? (Check as many as apply)**

- <sub>1</sub> Pain in your joints (arthritis)
- <sub>2</sub> Chest pain or discomfort (angina)
- <sub>3</sub> Pain in other parts of your body:

**SPECIFY:** \_\_\_\_\_

\_\_\_\_\_

---

*The next questions ask about the angina you may have had in the past month. Angina is a symptom of pain or discomfort that is due to the heart and is usually located in the chest, but may also be felt in the arms, back, neck, or jaw. Angina may feel like pain, pressure, soreness, heaviness or indigestion. It is not the soreness or discomfort felt around the chest incision after heart surgery.*

**20 A. Have you had any of these symptoms of angina in the past month?**

- <sub>1</sub> Yes ▶▶ Approximately how many times in the last week? \_\_\_\_\_
- <sub>2</sub> No ▶▶ **Go To Question 21**
- <sub>8</sub> DK

**B. Do you get it when you walk uphill or hurry?**

- <sub>1</sub> I don't walk uphill or hurry.
- <sub>2</sub> Yes
- <sub>3</sub> No ▶▶ **Go To Question 21.**
- <sub>8</sub> DK

**C. Do you get this pain or discomfort when you walk at an ordinary pace on level ground?**

- <sub>1</sub> Yes
- <sub>2</sub> No
- .....<sub>8</sub> DK

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**Question 21A-21D**

These items comprise the Rose Dyspnea Questionnaire and ask whether the patient has had shortness of breath in the past month and when it occurred. It descends from most to least exertion.

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**D. What do you do if you get this pain or discomfort when you are walking?  
(If you don't get it when you walk, Go To Question 21.)**

- <sub>1</sub> Stop, slow down or take nitroglycerin?
- <sub>2</sub> Continue walking without taking nitroglycerin ➡➡ **Go To Question 21.**
- <sub>8</sub> DK

**E. Does the discomfort go away?**

- <sub>1</sub> Yes ➡➡➡➡➡➡➡➡➡➡
- <sub>2</sub> No
- <sub>8</sub> DK

- <sub>1</sub> 10 minutes or less
- <sub>2</sub> More than 10 minutes

**21A. In the past month, have you been troubled by shortness of breath when hurrying on level ground or walking up a slight hill or one flight of stairs?**

- <sub>1</sub> Yes ➡➡ **Go To Question 21B**
- <sub>2</sub> No ➡➡ **Go To Question 22**
- <sub>8</sub> DK ➡➡ **Go To Question 21B**

**B. Do you get short of breath when walking with other people of your own age on level ground?**

- <sub>1</sub> Yes ➡➡ **Go To Question 21C**
- <sub>2</sub> No ➡➡ **Go To Question 22**
- <sub>8</sub> DK ➡➡ **Go To Question 21C**

**C. Do you have to stop for breath when walking at your own pace on level ground?**

- <sub>1</sub> Yes ➡➡ **Go To Question 21D**
- <sub>2</sub> No ➡➡ **Go To Question 22**
- <sub>8</sub> DK ➡➡ **Go To Question 21D**

**D. Do you get short of breath while you are washing, dressing, bathing or eating?**

- <sub>1</sub> Yes
- <sub>2</sub> No
- <sub>8</sub> Don't Know

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## Questions 22-27

These items assess the patient's work status. **Work is defined as a job for pay.** Persons are considered working if they are paid employees (paid in wages, salary, commission or "in kind"); self-employed in their own business profession, or in farming; or unpaid employees on a family business or farm. A person is retired if s/he considers himself/herself to be retired and is not looking for work. **Volunteer activities, activities around the house, or unpaid work such as for church should not be included as "work".**

### Question 22

This question is asked to determine the patient's working status just prior to his/her enrollment in OAT. If the patient indicates more than one category applies, ask him/her to choose the category which best describes his/her current working status. If the patient cannot decide, the category closest to the **top** of the list should be coded, e.g., part-time vs. retired should be coded "part-time" to indicate current employment.

- **It is important to elicit work dates, month and year; code DK, if "Don't Know".**
- Allow the **patient** to define "full-time" and "part-time"; the general rule is full-time  $\geq$  38 hours.
- If currently not working, ask date stopped, and if the date is **within the past six months**, proceed with the remaining work questions; otherwise, go to Question 28. If someone has not worked in the past 6 months, there is less likelihood of future employment.
- On **short-term sick leave** = on leave for **less** than 3 months due to **health reasons**.
- On **long-term sick leave** = on leave for **more** than 3 months due to **health reasons**.
- **Temporarily laid off** = patient is not currently working (for reasons **other** than health) but still has an employer. This designation is frequently used for "**seasonal laborers**" such as farmers, painters, builders, teachers, etc.
- **Disabled** = someone who **perceives** him/herself to be **disabled**, whether or not s/he is receiving medical disability.  
Note: workmen's compensation = disabled.
- **Unemployed (and /or) Looking for work:** "Looking for work" is actively seeking employment, any effort to procure a job or establish a business or profession.

### EXAMPLES:

- **Example 1:** A patient retired from his job as a factory worker two years ago, and now works 20 hours a week at McDonald's. S/he should be coded as "working part-time" since that is his/her current job activity.
- **Example 2:** A patient had been working full time until four weeks ago when s/he had a heart attack. S/he has not gone back to work. Since s/he has worked in the past three months, s/he should be coded as "on short term sick leave."
- **Example 3:** A patient has had progressive angina and has been on sick leave for four months, but has not formally retired. S/he should be coded as "on long-term sick leave."
- **Example 4:** Another patient has had progressive angina for the past three months and has had to quit his/her job because of his/her heart condition. Because s/he no longer has a job to return to, s/he is either "disabled" or "unemployed" (even if s/he intends to look for more work) or "retired."
- **Example 5:** A patient's only job is seasonally selling seed corn. S/he is not currently working and has not worked in the past 6 months, because it is not the working season. S/he should be coded as "temporarily laid off."

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## Questions 24-27

These questions define the patient's **job class**. It is important that a **detailed, descriptive job title and tasks** be written out along with number of hours worked. A patient's job class is more dependent on his job activities than his job title. Be careful to fill out **all** Mother-Child questions where applicable (e.g. "if yes..., if no...").

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**Questions 28-31 (Short Form-36)**

These questions, originally from the Medical Outcomes Study, comprise measures of role functioning, social functioning, and health perceptions.

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28. 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"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> |
| b. <u>Accomplished less</u> than you would like. . . . .  | <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> |
| c. Were limited in the <u>kind</u> of work or other activities . . . . .                                      | <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> |
| d. Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort). . . . . | <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> |

29. 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"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> |
| b. <u>Accomplished less</u> work than you would like . . . . .                 | <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> |
| c. Didn't do work or other activities as <u>carefully</u> as usual. . . . .    | <input type="checkbox"/> <sub>1</sub> | <input type="checkbox"/> <sub>2</sub> |

30. 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?

- <sub>1</sub> Not at all
- <sub>2</sub> Slightly
- <sub>3</sub> Moderately
- <sub>4</sub> Quite a bit
- <sub>5</sub> Extremely

31. 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                       |

---

**Questions 32-33 (Short Form-36)**

These questions, originally from the Medical Outcomes Study, comprise measures of psychological status, vitality and social function.

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*The next questions ask for your views about your health. If you are unsure about how to answer a question, please give the best answer you can.*

**32. 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

**33. 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.)?**

- <sub>1</sub> All of the time
- <sub>2</sub> Most of the time
- <sub>3</sub> Some of the time
- <sub>4</sub> A little of the time
- <sub>5</sub> None of the time

---

**Question 34A-J**

Time trade off utility items provide an alternative measurement of quality of life as measured by the patient's "recent" health in the past month. The introduction is thorough to help the patient understand the concept. If he/she seems to have extreme difficulty completing these items and does not understand after several attempts of interviewer assistance, make a note next to the items and on the Comments section of the Summary form and exit to Question 35. However, most patients can be helped to understand.

---

*This next set of questions deals with how you felt about your state of health in the past month. These questions are purely hypothetical and are being asked of all respondents. I will ask you whether you prefer living a certain amount of time in your current state of health versus a certain amount of time in excellent health. If you think the two choices are equal, please tell me so. For example, if I were to ask you, "Which would you prefer: living 10 more years in your current state of health or 10 more years in excellent health?" you would probably choose 10 more years in excellent health.*

**34. Please tell me which you would prefer...**

**A. Living about 10 years in your current state of health (as of last month) or living one half year in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 34B**  
<sub>2</sub> One half year in excellent health ➡➡ **Go To Question 35**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

**B. Living 10 years in your current state of health (as of last month) or living 9 years in excellent health, in other words, would you give up 1 year of life to live 9 years in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 35**  
<sub>2</sub> 9 years in excellent health ➡➡ **Go To Question 34C**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

**C. Living about 10 years in your current state of health (as of last month) or living only 1 year in excellent health? In other words, would you give up 9 years of life to live only 1 year in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 34D**  
<sub>2</sub> 1 year in excellent health ➡➡ **Go To Question 35**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

**D. Living about 10 years in your current state of health (as of last month) or living 8 years in excellent health, in other words, would you give up 2 years of life to live 8 years in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 35**  
<sub>2</sub> 8 years in excellent health ➡➡ **Go To Question 34E**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

**E. Living about 10 years in your current state of health (as of last month) or living only 2 years in excellent health? Would you give up 8 years of life to live 2 years in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 34F**  
<sub>2</sub> 2 years in excellent health ➡➡ **Go To Question 35**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

---

**Question 35**

This category rating scale 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.

---

**F. Living about 10 years in your current state of health (as of last month) or living 7 years in excellent health? Would you give up 3 years of life to live 7 years in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 35**  
<sub>2</sub> 7 years in excellent health ➡➡ **Go To Question 34G**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

**G. Living about 10 years in your current state of health (as of last month) or living only 3 years in excellent health? Would you give up 7 years of life to live 3 years in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 34H**  
<sub>2</sub> 3 years in excellent health ➡➡ **Go To Question 35**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

**H. Living about 10 years in your current state of health (as of last month) or living only 6 years in excellent health? Would you give up 4 years of life to live 6 years in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 35**  
<sub>2</sub> 6 years in excellent health ➡➡ **Go To Question 34I**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

**I. Living about 10 years in your current state of health (as of last month) or living only 4 years in excellent health? Would you give up 6 years of life to live 4 years in excellent health?**

- <sub>1</sub> 10 years in current health ➡➡ **Go To Question 34J**  
<sub>2</sub> 4 years in excellent health ➡➡ **Go To Question 35**  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ **Go To Question 35**

**J. Living about 10 years in your current state of health (as of last month) or living only 5 years in excellent health? In other words, would you give up 5 years of life to live 5 years in excellent health?**

- <sub>1</sub> 10 years in current health  
<sub>2</sub> 5 years in excellent health  
<sub>3</sub> Equal (indifferent or don't have preference)

**35. 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 36**

This question asks for the last grade of education or year completed. For example, if someone attended but did not complete the 11<sup>th</sup> grade, enter "10."

- The highest grade of school completed is defined as:

No schooling	=00
Grade School	=01-08
High School	=09-12
Technical School/College	=13-16
Professional or graduate school post college	=17-21+

**Examples**

- Completed 2 years of technical school or hospital RN =14
  - Got a law degree =19
  - Graduated from divinity school =19
  - Graduated from medical school =20
  - Has 2 master's degrees or any Ph.D. =sum of years in graduate school + 16
  - Any scenarios which are difficult to compute should be noted in the Comments section of the Baseline Summary Form.
- 

**Question 37**

This question 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.

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**Question 38**

**Be sure the patient** is included in this count of number in his/her household. This is a crude measure of the number of people dependent on the income of the household. For example, if a child is at college, but still "dependent" on the household for room and board, s/he is still part of the household. Also, if a household member is away for military service, s/he is still a part of the household if s/he regularly would live there. Document any unusual circumstances in the Comments section of the Summary.

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**Question 39**

This item is asking for the level of total household income, not actual amount.

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**Question 40**

This item assesses the number of significant income earners in order to estimate the contribution that the patient makes to the total household income (Q. 39).

- If either Question 39 or 40 is refused, **DO NOT PROBE**, but remind the patient again that the information will not affect their medical care and will not be reported to anyone (if that seems to be the problem); it is being asked solely for demographics for this study. If still refused, code = RF.
-



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

**36. What is the highest grade you finished in school? (Circle one.)**

- No School: 0
- Grade School: 1 2 3 4 5 6 7 8
- High School: 9 10 11 12 Equivalency Certificate
- College or Technical: 13 14 15 16
- Graduate or Professional: 17 18 19 20 21+

**37. Are you presently:**

- <sub>1</sub> Married or living as married
- <sub>2</sub> Divorced
- <sub>3</sub> Separated
- <sub>4</sub> Widowed
- <sub>5</sub> Never Married

**38. How many people, including yourself, live in your household? # \_\_\_\_\_ people**

*Finally, we would like to ask your total household income level. It will not affect your medical care in any way; it's strictly for demographic purposes for this study.*

**39. Roughly how much income from all sources (including earnings, pensions, investments, etc.) did your household have last year (before taxes)?**

- <sub>1</sub> \$10,000 or less
- <sub>2</sub> \$10,001 to \$20,000
- <sub>3</sub> \$20,001 to \$30,000
- <sub>4</sub> \$30,001 to \$45,000
- <sub>5</sub> \$45,001 to \$60,000
- <sub>6</sub> \$60,001 or greater
- <sub>8</sub> DK
- <sub>9</sub> RF

**40. Who were the major income earners in your household during the last year (this includes any retirement or fixed incomes)? (check all that apply)**

- <sub>1</sub> Myself
- <sub>2</sub> My spouse or spouse equivalent
- <sub>3</sub> My parents or in-laws
- <sub>4</sub> My children
- <sub>5</sub> Other individual(s)
- <sub>8</sub> DK
- <sub>9</sub> RF

## *OAT: Quality of Life*

### *Follow-Up and Proxy General Instructions*

***(Do not use the annotated or sample forms for patient administration;  
use forms provided by the DCRI EQOL group.)***

# EQOL-OAT Follow-Up General Instructions And Summary Protocol

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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 that can answer for the patient. (See *Proxy Instructions below*).

- If there are problems contacting a patient, please call the EQOL Center to discuss the particulars; it is critical that we keep patients in the study over the long-term.
- The questionnaire includes perceptions of health, assessment of physical function, psychological well-being, social support and work status. Assessment of symptoms, medical resource utilization, and expectations of coping with heart problems are included in the clinical Follow-Up OAT Forms. The questionnaire takes most of its content from the Baseline Questionnaire.
- Comparisons are being made **since the last EQOL contact**, which will be from the Baseline (for the 4 month EQOL/Clinical Follow-Up Forms) and from the last date of contact for the 12 month and 24 month intervals. It is important to know the patient's most recent follow-up information before talking with him/her. As always, anchoring the proper time frame is critical in order to obtain complete data, e.g., work status changes.

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## **Follow-Up Protocol**

- **Only guidelines of added items will be discussed. Previous guidelines for questions from the Baseline apply and will not be repeated here.**
  - ❖ **Question 23: Work Status:** This is an update of their work status at this point in time. Since the patient's last contact, whether baseline or follow-up.
  - ❖ **Question 33-34: Household Income:** These questions are asking for the patient to respond, in general terms as to whether their **income** has **changed** from the previous year and if it is enough to cover their basic needs.
- 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*).
- *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

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## **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.

---

### **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 determine if the person you are talking to is able and willing to answer medical utilization questions about the deceased.
- 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 speak English**, administer the appropriate Spanish or French QOL questionnaire.
- 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 unsuccessful, administer a proxy interview.

---

### **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 DCRI EQOL group.)***

# **EQOL - OAT FOLLOW-UP SUMMARY PROTOCOL**

A Summary must be completed at 4 months, 1 year, and 2 years for every patient randomized to EQOL OAT.

## **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 administered the Follow-Up Questionnaire. In specified instances, a proxy respondent is indicated. Medical record is only indicated if used to determine an alive/dead Follow-Up Status.

## **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 no phone interview is possible.

## **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.

**EQOL OAT Study**  
**Follow-Up Summary**

Patient Study #: \_\_\_\_\_-\_\_\_\_\_-\_\_\_\_

Patient Initials: \_\_\_\_\_

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

**FINAL QUESTIONNAIRE STATUS:**

- <sub>1</sub> Complete
- <sub>2</sub> Incomplete → → → → → → → →
- <sub>3</sub> Not Done → → → → → → → →

**SOURCE OF INFORMATION:**

- <sub>1</sub> Patient
- <sub>2</sub> Proxy
- <sub>3</sub> Translator Interview
- <sub>4</sub> Medical record

**REASON FOR INCOMPLETE OR NOT DONE:**

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

**FOLLOW-UP STATUS IF UTL/UTC:**

- <sub>1</sub> Alive → Date Last Contact Alive \_\_\_/\_\_\_/\_\_\_\_
- <sub>2</sub> Unknown → Date Last Contact Alive \_\_\_/\_\_\_/\_\_\_\_

**TYPE OF ADMINISTRATION:**

- <sub>1</sub> In person
- <sub>2</sub> Phone
- <sub>3</sub> Mail

**RESIDENCE** (of pt at time Summary Completed):

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

**INTERVIEWER:** \_\_\_\_\_

# EQOL OAT

Patient Study #: \_\_\_\_\_ - \_\_\_\_\_

Patient Initials: \_\_\_\_\_ - \_\_\_\_\_

## Follow-Up Quality of Life Questionnaire

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

*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: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

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

- <sub>1</sub> Excellent
- <sub>2</sub> Very Good
- <sub>3</sub> Good
- <sub>4</sub> Fair
- <sub>5</sub> Poor

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

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

**3. Which of the following statements describes the way you were in the prior month?**

- <sub>1</sub> My health allowed me to do anything I wanted to do.
- <sub>2</sub> My health allowed me to do almost anything I wanted to do.
- <sub>3</sub> I had trouble doing some ordinary activities.
- <sub>4</sub> I had trouble doing almost anything.

**4. In the past six weeks, about how many days did you stay in bed (while at home) for all or most of the day because of your health? # \_\_\_\_\_**

**5. Not counting the days you had to stay in bed, in the past six weeks, about how many days did you have to cut down on your usual activities because of your health? # \_\_\_\_\_**



*The next set of questions are about any physical limitations you might have had in the past month. For each question, please rate whether you are physically able to do one or more of the activities without difficulty, with some difficulty, you couldn't do it, or you don't do it for other reasons (NA).*

Could you. . .	<u>Yes, with no difficulty</u>	<u>Yes, but with some difficulty</u>	<u>No, I couldn't do this</u>	<u>NA</u>
6. take care of yourself, that is, eating, dressing, bathing, and using the toilet? . . . . .	1	2	3	7
7. walk indoors, such as around your house? . . . . .	1	2	3	7
8. walk a block or two on level ground? . . . . .	1	2	3	7

*For some of the rest of these activity questions, there will be more than one activity mentioned like climb a flight of stairs or walk up a hill. Answer each question according to the one activity you can do best.*

Could you. . .	<u>Yes, with no difficulty</u>	<u>Yes, but with some difficulty</u>	<u>No, I couldn't do this</u>	<u>NA</u>
9. climb a flight of stairs or walk up a hill? . . . . .	1	2	3	7
10. run a short distance? . . . . .	1	2	3	7
11. do light work around the house like dusting or washing dishes? . . . . .	1	2	3	7
12. do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries? . . . . .	1	2	3	7
13. do heavy work around the house like scrubbing floors or lifting or moving heavy furniture? . . . . .	1	2	3	7
14. do yard work like raking leaves, weeding, or pushing a power mower? . . . . .	1	2	3	7
15. have sexual relations? . . . . .	1	2	3	7
16. participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football? . . . . .	1	2	3	7
17. participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing? . . . . .	1	2	3	7

**18. How much bodily pain have you had during the past month?**

- <sub>1</sub> None
- <sub>2</sub> Very mild
- <sub>3</sub> Mild
- <sub>4</sub> Moderate
- <sub>5</sub> Severe
- <sub>6</sub> Very severe

**19. During the past month, how much did pain interfere with your normal work (including both work outside the home and housework)?**

- <sub>1</sub> Not at all
- <sub>2</sub> A little bit   ▶▶▶▶▶▶▶▶
- <sub>3</sub> Moderately   ▶▶▶▶▶▶▶▶
- <sub>4</sub> Quite a bit   ▶▶▶▶▶▶▶▶
- <sub>5</sub> Extremely   ▶▶▶▶▶▶▶▶

**What kind of pain was this? (Check as many as apply)**

- <sub>1</sub> Pain in your joints (arthritis)
- <sub>2</sub> Chest pain or discomfort (angina)
- <sub>3</sub> Pain in other parts of your body:

*SPECIFY:* \_\_\_\_\_  
 \_\_\_\_\_

*The next questions ask about the angina you may have had in the past month. Angina is a symptom of pain or discomfort that is due to the heart and is usually located in the chest, but may also be felt in the arms, back, neck, or jaw. Angina may feel like pain, pressure, soreness, heaviness or indigestion. It is not the soreness or discomfort felt around the chest incision after heart surgery.*

**20A. Have you had any pain or discomfort in your chest or arms in the past month?**

- <sub>1</sub> Yes ▶▶▶▶▶   **Approximately how many times in the last week? \_\_\_\_\_**
- <sub>2</sub> No ▶▶▶   **Go To Question 21**
- <sub>8</sub> DK

**B. Do you get it when you walk uphill or hurry?**

- <sub>1</sub> I don't walk uphill or hurry.
- <sub>2</sub> Yes
- <sub>3</sub> No   ▶▶▶   **Go To Question 21.**
- <sub>8</sub> DK

**C. Do you get this pain or discomfort when you walk at an ordinary pace on level ground?**

- <sub>1</sub> Yes
- <sub>2</sub> No
- <sub>8</sub> DK

**D. What do you do if you get this pain or discomfort when you are walking? (If you don't get it when you walk, Go To Question 21.)**

- <sub>1</sub> Stop, slow down or take nitroglycerin?
- <sub>2</sub> Continue walking without taking nitroglycerin ➡➡ **Go To Question 21.**
- <sub>8</sub> DK

**E. Does the discomfort go away?**

- <sub>1</sub> Yes ➡➡➡➡➡➡
- <sub>2</sub> No
- <sub>8</sub> DK

- <sub>1</sub> 10 minutes or less
- <sub>2</sub> More than 10 minutes

**21A. In the past month, have you been troubled by shortness of breath when hurrying on level ground or walking up a slight hill or one flight of stairs?**

- <sub>1</sub> Yes ➡➡ **Go To Question 21B**
- <sub>2</sub> No ➡➡ **Go To Question 22**
- <sub>8</sub> DK ➡➡ **Go To Question 21B**

**B. Do you get short of breath when walking with other people of your own age on level ground?**

- <sub>1</sub> Yes ➡➡ **Go To Question 21C**
- <sub>2</sub> No ➡➡ **Go To Question 22**
- <sub>8</sub> DK ➡➡ **Go To Question 21C**

**C. Do you have to stop for breath when walking at your own pace on level ground?**

- <sub>1</sub> Yes ➡➡ **Go To Question 21D**
- <sub>2</sub> No ➡➡ **Go To Question 22**
- <sub>8</sub> DK ➡➡ **Go To Question 21D**

**D. Do you get short of breath while you are washing, dressing, bathing or eating?**


- <sub>1</sub> Yes
- <sub>2</sub> No
- <sub>8</sub> DK

*The next questions are about your work status and daily activities.*

**22. Which one of the following best describes your work status NOW?**

- <sub>1</sub> Working full-time
- <sub>2</sub> Working part-time
- <sub>3</sub> On short-term sick leave
- <sub>4</sub> On long-term sick leave (at least three months)
- <sub>5</sub> Temporarily laid off
- <sub>6</sub> Homemaker
- <sub>7</sub> Disabled
- <sub>8</sub> Unemployed or looking for work
- <sub>9</sub> Retired
- <sub>10</sub> Other *Please specify:* \_\_\_\_\_

**23. Since the time of last contact, have you resumed working, stopped working or changed jobs or the type of work you do (for example, work more or fewer hours, take a desk job, quit a second job, retire)?**

- <sub>1</sub> Yes 
- <sub>2</sub> No

**What changed (check as many as apply)?**

- Stopped working because of my health...Date: \_\_/\_\_/\_\_
- Stopped working for some other reason..Date: \_\_/\_\_/\_\_
- Resumed working.. .....Date: \_\_/\_\_/\_\_
- Working more hours
- Working fewer hours
- Doing more strenuous work
- Doing less strenuous work
- Went on long or short term sick leave
- Temporarily laid off
- Other: \_\_\_\_\_

**24. 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?**

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

25. 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)?

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

26. 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?

- <sub>1</sub> Not at all
- <sub>2</sub> Slightly
- <sub>3</sub> Moderately
- <sub>4</sub> Quite a bit
- <sub>5</sub> Extremely

27. 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

*The next questions ask for your views about your health. If you are unsure about how to answer a question, please give the best answer you can.*

**28. 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

**29. 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.)?**

- <sub>1</sub> All of the time
- <sub>2</sub> Most of the time
- <sub>3</sub> Some of the time
- <sub>4</sub> A little of the time
- <sub>5</sub> None of the time

30. This next set of questions deals with how you felt about your state of health in the past month. These questions are purely hypothetical and are being asked of all respondents. I will ask you whether you prefer living a certain amount of time in your current state of health versus a certain amount of time in excellent health. If you think the two choices are equal, please tell me so. For example, if I were to ask you, "Which would you prefer: living 10 more years in your current state of health or 10 more years in excellent health?" you would probably choose 10 more years in excellent health.

*Now, please tell me which you would prefer...*

- A. Living 10 years in your current state of health (as of last month) or living one half year in excellent health?

- <sub>1</sub> 10 years in current health ➡➡ Go To Question 30B  
<sub>2</sub> One half year in excellent health ➡➡ Go To Question 31  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

- B. Living about 10 years in your current state of health (as of last month) or living 9 years in excellent health, in other words, would you give up 1 year of life to live 9 years in excellent health?

- <sub>1</sub> 10 years in current health ➡➡ Go To Question 31  
<sub>2</sub> 9 in excellent health ➡➡ Go To Question 30C  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

- C. Living about 10 years in your current state of health (as of last month) or living 1 years in excellent health, in other words, would you give up 9 years of life to live 1 year in excellent health?

- <sub>1</sub> 10 years in current health ➡➡ Go To Question 30D  
<sub>2</sub> 1 year in excellent health ➡➡ Go To Question 31  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

- D. Living about 10 years in your current state of health (as of last month) or living only 8 years in excellent health? In other words, would you give up 2 years of life to live only 8 years in excellent health?

- <sub>1</sub> 10 years in current health ➡➡ Go To Question 31  
<sub>2</sub> 8 years in excellent health ➡➡ Go To Question 30E  
<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

- E. Living about 10 years in your current state of health (as of last month) or living 2 years in excellent health? Would you give up 8 years of life to live 2 years in excellent health?

- <sub>1</sub> 10 years in current health ➡➡ Go To Question 30F  
<sub>2</sub> 2 years in excellent health ➡➡ Go To Question 31

<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

Patient Study #: \_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_

**F. Living about 10 years in your current state of health (as of last month) or living only 7 years in excellent health? Would you give up 3 years of life to live 7 years in excellent health?**

<sub>1</sub> 10 years in current health ➡➡ Go To Question 31

<sub>2</sub> 7 years in excellent health ➡➡ Go To Question 30G

<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

**G. Living about 10 years in your current state of health (as of last month) or living only 3 years in excellent health? Would you give up 7 years of life to live 3 years in excellent health?**

<sub>1</sub> 10 years in current health ➡➡ Go To Question 30H

<sub>2</sub> 3 years in excellent health ➡➡ Go To Question 31

<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

**H. Living about 10 years in your current state of health (as of last month) or living only 6 years in excellent health? Would you give up 4 years of life to live 6 years in excellent health?**

<sub>1</sub> 10 years in current health ➡➡ Go To Question 31

<sub>2</sub> 6 years in excellent health ➡➡ Go To Question 30I

<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

**I. Living about 10 years in your current state of health (as of last month) or living only 4 years in excellent health? Would you give up 6 years of life to live 4 years in excellent health?**

<sub>1</sub> 10 years in current health ➡➡ Go To Question 30J

<sub>2</sub> 4 years in excellent health ➡➡ Go To Question 31

<sub>3</sub> Equal (indifferent or don't have preference) ➡➡ Go To Question 31

**J. Living about 10 years in your current state of health (as of last month) or living only 5 years in excellent health? In other words, would you give up 5 years of life to live 5 years in excellent health?**

<sub>1</sub> 10 years in current health

<sub>2</sub> 5 years in excellent health

<sub>3</sub> Equal (indifferent or don't have preference)

**31. 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? # \_\_\_\_\_**



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

32. How many people, including yourself, live in your household? # \_\_\_\_\_ people

33. Is your current monthly household income more, less or about the same as a year ago?

- <sub>1</sub> More
- <sub>2</sub> Less
- <sub>3</sub> About the same
- <sub>8</sub> DK
- <sub>9</sub> RF

34. How well does your household's income meet your household's basic needs (i.e., food, clothing, shelter, and medical expenses, including medicines)?

- <sub>1</sub> Not at all
  - <sub>2</sub> Somewhat
  - <sub>3</sub> Adequately
  - <sub>4</sub> More than adequately
  - <sub>8</sub> DK
  - <sub>9</sub> RF
-



# EQOL OAT

## Follow-Up Proxy Questionnaire

Patient Study #: \_\_\_ - \_\_\_ - \_\_ - \_\_\_ - \_\_\_

Patient Initials: \_\_\_\_ - \_\_\_\_

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

*The following questions are about his/her overall health and recent activities. Answer each question as best you can.*

Today's Date: \_\_\_ / \_\_\_ / \_\_\_

Relationship of person providing information: (circle one)

- |                                |                                 |
|--------------------------------|---------------------------------|
| 1. Spouse                      | 8. Cousin                       |
| 2. Daughter/ Son               | 9. Other Relative               |
| 3. Son-in-law/ Daughter-in-law | 10. Friend                      |
| 4. Grandchild                  | 11. Boarder/ Renter             |
| 5. Parent of Patient           | 12. Health Aide                 |
| 6. Brother/ Sister             | 13. Other Unrelated             |
| 7. Nephew/ Niece               | 14. Staff member at institution |
|                                | 15. Self                        |

*The first few questions are about any physical limitations he/she might have had in the month before his/her hospitalization. For each question, please rate whether he/she could do one or more of the activities without difficulty, with some difficulty, or he/she couldn't do it, or he/she doesn't do it for some other reason (NA).*

Could he/she. . .	<u>Yes, with no difficulty</u>	<u>Yes, but with some difficulty</u>	<u>No, he/she couldn't do this</u>	<u>NA</u>
1. take care of yourself, that is, eating, dressing, bathing, and using the toilet? . . . . .	1	2	3	7
2. walk indoors, such as around your house? . . .	1	2	3	7
3. walk a block or two on level ground? . . . . .	1	2	3	7

*For some of the rest of these activity questions, there will be more than one activity mentioned like climb a flight of stairs or walk up a hill. Answer each question according to the one activity he/she can do best.*

	<u>Yes, with no difficulty</u>	<u>Yes, but with some difficulty</u>	<u>No, he/she couldn't do this</u>	<u>NA</u>
<b>Could he/she. . .</b>				
4. climb a flight of stairs or walk up a hill? . . . . .	1	2	3	7
5. run a short distance? . . . . .	1	2	3	7
6. do light work around the house like dusting or washing dishes? . . . . .	1	2	3	7
7. do moderate work around the house like vacuuming, sweeping floors, or carrying in groceries? . . . . .	1	2	3	7
8. do heavy work around the house like scrubbing floors or lifting or moving heavy furniture? . . . . .	1	2	3	7
9. do yard work like raking leaves, weeding, or pushing a power mower? . . . . .	1	2	3	7
10. participate in moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football? . . . . .	1	2	3	7
11. participate in strenuous sports like swimming, singles tennis, football, basketball, or skiing? . . . . .	1	2	3	7

*The next questions ask about the angina and shortness of breath he/she may have had in the past month. Angina is a symptom of pain or discomfort that is due to the heart and is usually located in the chest, but may also be felt in the arms, back, neck or jaw. Angina may feel like pain, pressure, soreness or indigestion. It is not the soreness or discomfort felt around the chest incision after heart surgery.*

**12. Has he/she had any pain or discomfort in his/her chest or arms in the past month?**

- <sub>1</sub> Yes ➡➡➡ **Approximately how many times in the last week? \_\_\_\_\_**
- <sub>2</sub> No
- <sub>8</sub> DK

**13. Has he/she had any shortness of breath in the past month while washing, dressing, bathing or eating?**

- <sub>1</sub> Yes
- <sub>2</sub> No
- <sub>8</sub> DK

**14. What is his/her current working status?**

- <sub>1</sub> Working full-time
  - <sub>2</sub> Working part-time
  - <sub>3</sub> On short-term sick leave
  - <sub>4</sub> On long-term sick leave (at least three months)
  - <sub>5</sub> Temporarily laid off
  - <sub>6</sub> Homemaker
  - <sub>7</sub> Disabled
  - <sub>8</sub> Unemployed or looking for work
  - <sub>9</sub> Retired
  - <sub>10</sub> Other *Please specify:* \_\_\_\_\_
- 

*Lastly, for our records, just a few questions about him/her.*

**15. How many people, including him/her self, live in his/her household? # \_\_\_\_\_ people**

**16. Is his/her current monthly household income more, less or about the same as a year ago?**

- <sub>1</sub> More
- <sub>2</sub> Less
- <sub>3</sub> About the same
- <sub>8</sub> DK
- <sub>9</sub> RF

**17. How well does his/her household income meet their household's basic needs (i.e., food, clothing, shelter, and medical expenses, including medicines)?**

- <sub>1</sub> Not at all
- <sub>2</sub> Somewhat
- <sub>3</sub> Adequately
- <sub>4</sub> More than adequately
- <sub>8</sub> DK
- <sub>9</sub> RF



## OAT -EQOL 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 EQOL RESEARCH GROUP\***

## OAT -EQOL 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 EQOL 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 EQOL RESEARCH GROUP\***



# OAT - EQOL Magnet

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The primary purpose of the EQOL Outcomes Magnet is to facilitate phone follow-up interviewing with patients.

- ◆ The EQOL Outcomes Magnet is used in several studies at the DCRI; for EQOL OAT only sections **A**, **B**, and **C** response options are applicable.
- ◆ **Distribute a magnet to each patient when enrolled.** Encourage the patient to keep it on their refrigerator to help them with the follow-up interviews. You may also find the magnet beneficial when administering the Baseline Questionnaire.
- ◆ Listed below are the questions on the Baseline, Follow-Up and Proxy Questionnaires that correspond to each set of response options on the magnet.

## **Baseline Questionnaire:**

- ◆ Questions **6-17** will use responses from **A**.
- ◆ Question **31** will use responses from **C**.
- ◆ Question **32** will use responses from **B**.

## **Follow-up Questionnaire:**

- ◆ Questions **6-17** will use responses from **A**.
- ◆ Question **27** will use responses from **C**.
- ◆ Question **28** will use responses from **B**.

## **Follow-up Proxy Questionnaire:**

- ◆ Questions **1-11** will use responses from **A**.

**If you have Questions or Problems using this tool, please call us at (919) 668-8430**



# EXAMPLE OF THE MONTHLY EQOL OAT FORMS SCHEDULER

## EQOL OAT FORMS and BILLS SCHEDULER

Tuesday, January 30, 2001

Site No.: 000  
Site Name: University Health Care

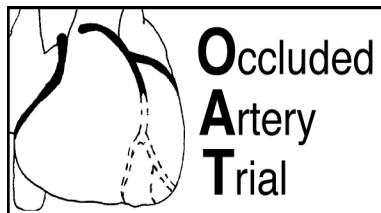
Attention: **Study Coordinator**  
Fax: (999) 999-9999  
Phone: (999) 999-9999

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	Date	Due	Note
000-002	01/22/2001	WS	QOL	Baseline QOL Summary/Questionnaire		01/22/2001	Due
			01/22/2001	Consent	Signed Patient Consent Form		Due
000-003	01/25/2001	AM	QOL	4 month QOL Summary/Questionnaire		04/25/2001	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.



**DATA CLARIFICATION SAMPLE FORM**

EQOL OAT  
**January 24, 2001**

**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

## OAT: Economic Data

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### Hospital Bill Collection (USA only)

- ◆ Bills are to be collected by the DCRI. Sites will not have to collect any patient bills.
- ◆ In order for the DCRI to collect bills, the site is responsible for faxing a copy of each **patient's signed consent form** with the Baseline QOL Questionnaire. Please fax to (919) 668-7054.
- ◆ Please make sure the **patient name** is printed legibly on the consent form.
- ◆ Once the consent is received, the DCRI will then contact the Billing /Patient Account Department at your institution to collect the bill information for the patient. As per patient consent, bills are collected from any Baseline hospitalization through the length of the study.
- ◆ **Questions?** Call us at (919) 668-8430.