

Subject ID: _____

SAMPLE: SPRY Clinical Research Form

SPRY-Metformin 30 Day Assessment

Interviewer: Please complete before start of the interview. Enter subject ID # on the top of every page

Follow up telephone call attempts will be made for the contact using discretion and judgment of the LTO personnel.

Date of SPRY Enrollment (MMDDYY)	
Date of Study Surgery (MMDDYYYY)	
Date of current interview (MMDDYYYY)	
Interview conducted with:	<input type="checkbox"/> Subject <input type="checkbox"/> Surrogate/LAR If Interview conducted with surrogate, please indicated reason: <input type="checkbox"/> subject too ill/in a medical facility <input type="checkbox"/> Subject Death (Date: / /) <input type="checkbox"/> Other _____

Hello, I am [NAME] calling from the SPRY Study that you agreed to participate in prior to your surgical procedure. I'm calling you today to see how you are doing and to conduct the survey with you for the study. Is this a good time? We anticipate the total time for this call to be about 10-15 minutes.

If no: "When is the best time to reach you? Do you have a preference what time of day we call?"

If yes: Wonderful. First let me remind you a bit about the purpose of the study

Purpose: The purpose of this study is to test how well different doses and durations of the study medication "Metformin" may improve how people without diabetes do after having their surgical procedure. Today I'm just going ask you some questions about any medical services you may have used following your surgery as well as some questions about your use of the study medication and how you are feeling in general.

Section 1: Post-discharge Resource Use

Interviewer: If patient not yet discharged from surgical hospital, skip to Section 2

- When you were discharged from the hospital following your surgery, did you go home right away or did you first stay **overnight in a different hospital or medical facility**?
 - Home (subject's normal domicile i.e. nursing home, assisted living, group home)
 - Home with medical assistance (home health care)
 - Another hospital or medical facility (new to subject)
 - Other: _____
 - Don't Know
 - Not discharged from surgical hospital

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- Refused to answer

Interviewer: [if "Home"] proceed to Question 3

2. [If discharged to [Another Hospital or Medical Facility] to which type of facility did [patient's name] go after hospital discharge (choose all that apply if patient has been sent to multiple facilities since discharge from surgical hospital)?

Total Days admitted _____

- | | | |
|--------------------------------|----------------------------|------------------|
| Another Hospital | <input type="checkbox"/> 1 | # admt _____ |
| | | Total Days _____ |
| Rehabilitation Center | <input type="checkbox"/> 2 | # admt _____ |
| | | Total Days _____ |
| Hospice (hospice facility) | <input type="checkbox"/> 3 | # admt _____ |
| | | Total Days _____ |
| LTAC | <input type="checkbox"/> 4 | # admt _____ |
| | | Total Days _____ |
| SNF | <input type="checkbox"/> 5 | # admt _____ |
| | | Total Days _____ |
| Other (<i>specify</i>) _____ | <input type="checkbox"/> 6 | # admt _____ |
| | | Total Days _____ |
| Don't Know | <input type="checkbox"/> | |
| Refused | <input type="checkbox"/> | |

3. Since being discharged to home, have you been admitted to a hospital OVERNIGHT? (*Do not include an overnight stay in the emergency room.*)

- Yes
 No
 Don't know
 Refused to Answer

4. [If yes] What was the name(s) of the hospital(s) to which you were readmitted?

- Don't Know
 Refused to answer

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Section 2: Quality of Life

Interviewer : Now I will ask you questions about your general health. Please indicate which statements best describe your own health today.

Mobility

- I have no problems walking
- I have some problems walking
- I am confined to bed

Self-Care

- I don't have problems caring for myself
- I have some problems washing or dressing myself
- I can't wash or dress myself

Usual Activities (like work, housework, family activities)

- I don't have problems performing my usual activities
- I have some problems performing my usual activities
- I can't perform my usual activities

Pain and Discomfort

- I don't have pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety and Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

PART TWO

Now, on a scale from 0 to 100, where 100 represents the best imaginable health while 0 represents the worst possible health you could imagine, at what number would you rate your health in general **now?** (Interviewer, mark number on scale to the right and write the number given by the subject)

Answer: _____

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Interviewer: Now I'm going to ask you some questions about your current employment status. We are interested in whether you have recovered from your recent surgery and hospitalization sufficiently to return to work or your usual activities. Please choose the answer that most closely describes your situation right now

Right now, my work and/or usually activity is:

- Full-time employment
- Part time employment
- Homemaker
- Retired
- Unemployed due to disability or illness
- Unemployed due to job loss and/or inability to find work
- Student
- Other
- Unknown (proxy response)

This work and/or usual activity is:

- The same as before my surgery
- Different from before my surgery due to effects from the surgery
- Different from before I was hospitalized, but not due to my surgery
- Unknown (proxy response)

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Section 3: Use of Study Medication

Interviewer: I am now going to ask you some questions about your use of the study medication.

1. Since your discharge from the hospital following your surgery, have you temporarily or permanently stopped taking your study medication at any time?
 Yes, Temporarily _____ (# of days stopped) Yes, permanently _____ (date stopped)
 No
2. Since your discharge from the hospital following your surgery, are there any days or times that you missed or forgot to take your study medication? Yes No
3. (If yes) How many doses of your study medication would you say you missed or forgot to take since you were discharged from the hospital after your surgery? _____ (# of doses)

End of Interview: Thank you for your time today. As a reminder, there is one final follow-up call/visit for this study which takes place in approximately 2 months from now. Would you be able to schedule that call/visit now?

(If a telephone follow-up): The call will take approximately 30 minutes and we'll ask you similar questions to today's call with some additional questions surrounding your memory and thinking.

(If in person follow-up): We estimate the time of the visit to be approximately 1.5 hours where we will do some tests of your thinking as well as your physical function. The visit will take place in our Critical Care Offices in Oakland.