FGS_____ FGS FORM: FGS103 VERSION: 051603 DATA ENTRY INTL.:

Monthly Telephone Questionnaire

Participant ID:	FGS-			
Interviewer ID:				
Date of Interview:				
	I	MONTH	DAY	YEAR
Length of Interview:				Minutes
Length of Interview: No. of Sessions:				Minutes



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Monthly Telephone Questionnaire FGS_____ FGS FORM: FGS103 VERSION: 051603 DATA ENTRY INTL.: _____

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Monthly Telephone Questionnaire

Time Began: : AM PM

A. INTRODUCTORY SCRIPT

Hello. I am (name of interviewer) and I am calling to talk with ______. Is this ______. Is this

Hello _______ and I am calling based on your participation in the Fibroid Growth Study. I would like to ask you questions about your health and lifestyle during the past month. This will take about 15 minutes. Do you have the time now for me to ask you these questions?

[If not], when would be a better time to call?

Many of the questions are very personal. You do not have to answer any questions if you feel they are too personal or that you do not want to answer for any reason. This will not affect your participation in the study itself.

Feel free to ask questions if you do not understand the question or would like to know why we ask such questions.

Do you have any questions right now? Could you get a calendar to have near the phone to help with some of the questions, and if you have a record of your menstrual period, could you get that and keep it handy as well?

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Monthly Telephone Questionnaire B. Medical Information

	The first question is about pregnancy.		
B1.	Do you think you are currently pregnant?	Yes	1
		No	
		Refused	8
		Don't know	
	The next questions are about vaginal bleeding.		
B2	During the last 30 days, how much of a problem was vaginal	Big	
DZ.	bleeding (including menstruation) for you?	Medium	
	blocking (including mensituation) for you?	Small	
		None	
		Refused	
		Don't know	
		Don't know	9
B3	During the last 30 days how much did vaginal bleeding interfere	A lot	1
DJ .	with your daily responsibilities, such as going to work/caring	Some	
	for family members and doing housework?	A little	-
	IOI family members and doing housework?		
		Not at all	4
		Refused	8
		Don't know	9
R/	During the last 30 days how much did vaginal bleeding limit	A lot	1
04.	your social activities, such as visiting friends, taking vacations,	Some	
	· · ·	A little	
	having company?		
		Not at all	4
		Refused	8
	T	Don't know	9
	The next questions are about some symptoms you may have had during the last 30 days.		
D5	During the last 30 days how much of the time have you felt	All or Most of the time	1
БЭ.	• • •	Some of the time	
	excessively tired?		_
		A little of the time	
		None of the time	4
		Refused	8
		Don't know	9
B6	During the last 30 days, how much of the time have you had	All or Most of the time	1
20.	back pain?	Some of the time	
		A little of the time	
		None of the time	
		Refused	
		Don't know	_
			9
	The next two questions ask you to recall the number of days		
R7	During the last 30 days, about how many days did you have		
07.			
	cramps, discomfort or pain the pelvic area?		No. of days
DO	During the last 20 days, shout how many days did you have a		
۵ö.	During the last 30 days, about how many days did you have a		
	feeling of heaviness in the pelvic area?		No. of days



Monthly	Telephone
Quest	ionnaire

B9.	During the last 30 days, how much of a problem was pelvic	A big problem
	heaviness, discomfort, or pain for you? Was it:	Medium Problem

201	0	s, discomfort, or pain for you? Was it:	Medium Problem Small Problem No Problem Refused Don't know	2 3 4 8 9
B10.	discomfor	e last 30 days, how much did pelvic heaviness t or pain interfere with your being able to do you like to do or have to do? Did it interfere:	A lot Some A little Not at all Refused Don't know	1 2 3 4 9
	B11.	If at least "a little"; were there days when you just had to stay home because of pelvic discomfort or pain?	Yes No Refused Don't know	1 2 8 9
	B12.	IF YES: In the last 30 days how many days did you stay home because of pelvic discomfort or pain?		No. of days
B13.	During the constipate	e last 30 days how much of the time have you been ed?	All or most of the time Some of the time A little of the time None of the time Refused Don't know	1 2 3 4 9
B14.	. Do you ta IF YES T	ke laxatives, such as Metamucil, on a regular basis?	Yes No Refused Don't know	1 2 8 9
	B15.	What is your reason for taking laxatives? Is it because you are having a problem, or is it part of your regular habits?	Having a problem Regular habits Refused Don't know	1 2 8 9
B16.	. During the of gas?	e last 30 days how much of the time have you had a lot	All or most of the time Some of the time A little of the time None of the time	1 2 3 4

Refused

Don't know



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B17. During the last 30 days how much of the time have you had stomach aches or nausea?	All or most of the time1Some of the time2A little of the time3None of the time4Refused9Don't know9	
B18. During the last 30 days have you ever had a urine leak?	Yes1 No2 Refused8 Don't know9	
IF YES TO B18		
B19. How much of a problem was it?	A big problem 1 Medium Problem 2 Small Problem 3 No Problem 4 Refused 8 Don't know 9	
B20. Was it due to coughing, laughing, sneezing or lifting? Or was it just an uncontrolled response?	Laughing, etc.	
B21. During the last 30 days, did you sometimes feel like you needed to urinate urgently, even though you had little or no warning?	Yes	
B22. How much of a problem was it?	A big problem	
Now I am going to ask you about your general health.		
B23. In the last 30 days, have you had a cold or been sick?	Yes1 No2 Refused8 Don't know9	
B24. Did you have a fever?	Yes	

			Monthly Telephone Questionnaire	DATA ENTRY INTL.:			
B25.	5. In the last 30 days, have you visited a doctory or been hospitalized?		r	Yes, Visited doctor Yes, In the hospital No Refused Don't know	·····.1 ·····2 ·····3 ····8 ····9		
	IF YES to	B25					
	B26.	What was the reason?					
		Please write reason exactly as stated.					

B27. What examination procedures were done for you during your doctor or hospital visit?

Please write procedures exactly as stated.

The next question is about scheduled treatment, including surgery. We wish to stress that any decisions about treatment should be made by you. Your decision is not related to study participation. However, it is helpful for us to be informed when a study participant has chosen a treatment option. In the last month, have you been scheduled to

B28. receive treatment (including surgery) for your fibroids?

	Yes No Refused Don't know	1 2 8 9
B29. If yes: What type of treatment is scheduled?	Hysterectomy Myomectomy Embolization Other:	1 2 3 4
	Specif Refused	8
	Don't know	9
B30. If yes: Has a date of the surgery been set?	Yes No Refused Don't know	1 2 8 9

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	Fibroid Growth St Monthly Telephone Questionnaire	-	Idy FGS FGS FORM: FGS103 VERSION: 051603 DATA ENTRY INTL.:			
B31.	If yes: What is the date of the surgery?	Month	Day	Year		
	Writ	te out Mont	:h			
	The next three questions are about infections.					
B32.	In the last 30 days, have you had cold sores (Fever sores, fever blisters)?	Yes No Refused Don't knov	N		2 8	
B33.	In the last 30 days, have you had canker sores (mouth sores or mouth ulcers)?	Yes No Refused Don't know	N			
B34.	In the last 30 days, have you had genital herpes sores or blisters?	Yes No Refused Don't know	N		2 8	
	C. PHYSICAL ACTIVITY					
	The next questions are about vigorous activity.					
C1.	Currently do you engage in vigorous recreational activities that increase your heart rate or make	Yes No				

C2. How many times per week do you engage in vigorous recreational activity?

you sweat for at least 30 minutes at a time?

Now I'd like to ask you about time that you spend walking to work, during lunch or shopping, as well as recreational walking.

Refused

Don't know

Don't know

C3. During a typical day, how much time do: you spend walking? Between Between Up to ½ hour 1 ½ hour and an hour 1 ½ hour and 1 ½ hour 1 ½ hour and 2 hours 2 and 2 ½ hours 2 ½ and 3 hours More than 3 hours Refused ...

•	-	•	•	-	-	•	•	•	•	•	•	•	•	•	1 2 3
															4
															5
			•	•			•	•					•		6
•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	7
•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	8
•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	9

.

.

No. of times

. 8

....9

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Monthly Telephone Questionnaire

D. DIET

D1.	How often do you eat red meat?	Daily 3-6 times per 1-2 times per Less than on Never	week		1 2 3 4 5
D2.	Not counting fruit juices, how many servings of fruits and vegetables do you eat per day?	5 + per day 3-4 per day 1-2 per day <1 per day		· · · · · · · · · · · · · · · · · · ·	1 2 3 4
D3.	How often do you eat at fast food restaurants?	Daily 3-6 times per 1-2 times per Less than on Never	week	·····	1 2 3 4 5
D4.	How often do you eat fried foods?	Daily 3-6 times per 1-2 times per Less than on Never	week	· · · · · · · · · · · · · · · · · · ·	1 2 3 4 5
D5.	Thinking about the last 30 days, how many caffeinated beverages did you drink each day, each week, or over the month?	per month	per week	or	per day
D6.	In the last 30 days, how many alcoholic beverages (beer, wine or liquor) did you drink each day, each week, or over the month?	per month	per week	or	per day
D7.	In the last 30 days, were there any days when you didn't eat or drink anything except water or other drinks without calories?	Yes No Refused Don't know			1 2 8 9
					=

IF YES

D8. How many days?

The next questions are about diet.

No. of days



Monthly Telephone Questionnaire

		-		
D9. During an	ny of the last 30 days, have you been on a diet?	Yes No Refused Don't know		1 2 8 9
IF YES TO D10.	O D9 Which of the following types diets were you on? You can choose one or more than one category	Low calorie Low fat Low carbohydrate Vegetarian High protein like the Atk Liquid diet like Slim Fas Other (please specify)	tins Diet t	2 3 4 5 6
	t 30 days, have you been taking diet pills?	Refused Don't know Yes No Refused Don't know		8 9 1 2 8 9
IF YES D12.	What type of diet pill did you take?			
The next	questions are about your weight.			
D13. Did you lo gained it l	ose any weight in the last 30 days even if you back?	Yes No Refused Don't know	·····	1 2 8 9
IF YES				# of Ibs.

D14. How many lbs.?

D15. What is your current weight?

D16. Thinking of the last 30 days, how many cigarettes did you smoke per day, on average?

of lbs.

per day

FGS FGS FORM: FGS103 VERSION: 051603 DATA ENTRY INTL.:

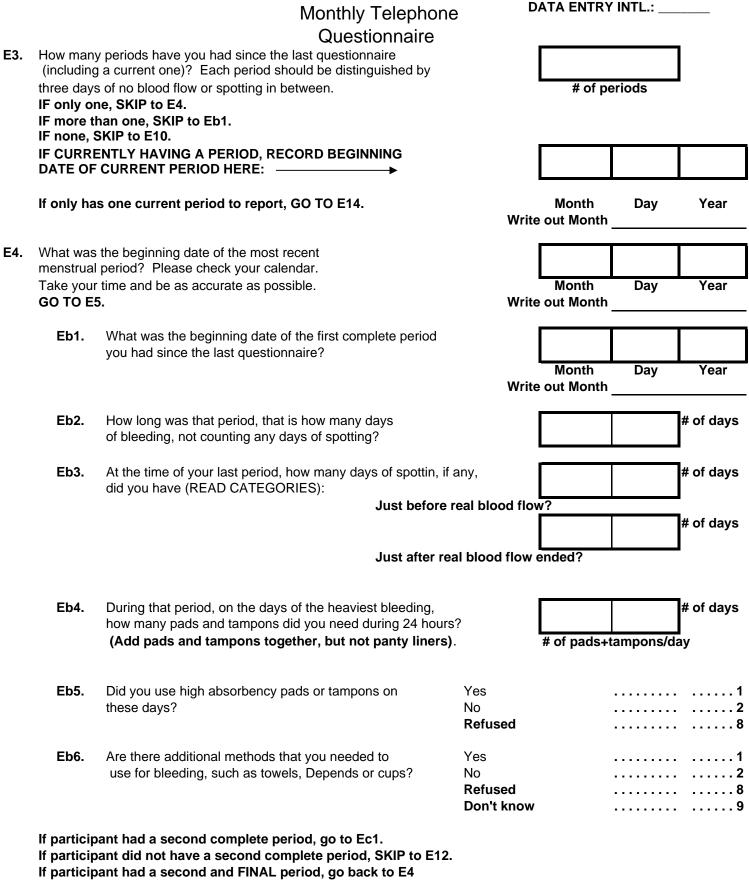
Monthly Telephone Questionnaire

E. MENSTRUATION

REVIEW LAST MONTH'S QUESTIONNAIRE IN ORDER TO DETERMINE WHEN LAST MENSTRUAL PERIOD OCCURRED. IF COMPLETE HISTORY WAS REPORTED DURING LAST QUESTIONNAIRE BEGIN WITH E1. IF PARTICIPANT WAS IN THE MIDDLE OF A MENSTRUAL PERIOD DURING LAST QUESTIONNAIRE, BEGIN WITH E2.

E1.		you reported having a menstrual period	Yes	1
	starting of		No	
		any periods since this one? (IP to E10.	Refused Don't know	(GO TO E10)8 (GO TO E10)9
	•	KIP to E3.	DONTKHOW	(GO TO ETO9
	11 123, 3	RIP to E3.		
E2.	Last time	you reported having a menstrual period starting		
	on	(month/day) and then another that		
		tarted on(month/day). You		
	had not y	et finished that one, so I'd like to ask about it now.		
		was that period, that is how many days		# of days
	of bleedin	g, not counting any days of spotting?		
	Ea1.	At the time of your last period, how many days of spottir	ng, if any.	# of days
		did you have (READ CATEGORIES):	5, y,	
		Just befo	re real blood flow?	
				# of days
		Just after	r real blood flow ended	1?
	Ea2.	During that period, on the days of the heaviest bleeding.		
		how many pads and tampons did you need during 24 ho		
(Add	d pads and	tampons together, but not panty liners).	# of	pads+tampons/day
	Ea3.	Did you use high absorbency pads or tampons on	Yes	1
		these days?	No	2
			Refused	8
	Ea4.	Are there additional methods that you needed to	Yes	1
		use for bleeding, such as towels, Depends or cups?	No	2
			Refused	
			Don't know	9

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	Now I an	Fibroid Growth Monthly Telepho Questionnaire n going to ask you about the second complete period	one ^I	VEF DATA ENTRY		
	Ec1.	What was the beginning date of the second complete pe had since the last questionnaire?	-		•	
			Writ	Month e out Month	Day	Year
	Ec2.	How long was your second period, that is how many day of bleeding, not counting any days of spotting?				# of days
	Ec3.	At the time of your last period, how many days of spottin did you have (READ CATEGORIES):	g, if any,			# of days
		,	re real blood flo	w?		
		Just after	real blood flow	ended?		# of days
	Ec4.	During your second period, on the days of the heaviest bleeding, how many pads and tampons did you need during 24 hours? (Add pads and tampons together, but not panty liners).		# of pads+t	ampons/da	ау
	Ec5.	Did you use high absorbency pads or tampons on these days?	Yes No Refused			1 2 8
	Ec6.	Are there additional methods that you needed to use for bleeding, such as towels, Depends or cups?	Yes No Refused Don't know	1		1 2 8 9
	If particip	ant had a third and final period, go to E4.				
E5.	•	was your most recent complete period, that is how many og, not counting any days of spotting?	days			# of days
E6.		e of your last period, how many days of spottin, if any, ave (READ CATEGORIES):				# of days
	-	Just befo	re real blood flo	w?		# of days
		.lust after	real blood flow	ended?		# OI UdyS
E7.		ur most recent period, on the days of the heaviest bleeding v pads and tampons did you need during 24 hours?				
		Is and tampons together, but not panty liners).		# of pads+t	ampons/da	ау
E8.	Did you u	se high absorbency pads or tampons on these days?	Yes No Refused			1 2 8

	Fibroid Growth	Study	FGS FGS FORM: FGS103 VERSION: 051603
	Monthly Teleph	one DAT	A ENTRY INTL.:
	Questionnaire		
F9 Are then	e additional methods that you needed to use for bleeding,	Yes	1
	towels, Depends or cups?	No	
		Refused	8
		Don't know	9
If there	are no more periods to report, SKIP TO QUESTION E1	2	
The nex	t questions are about vaginal bleeding.		
E10. Have yo	ou had any vaginal bleeding in the last 30 days?	Yes	1
		No	2
lf vos a	jo to E11.	Refused Don't know	8
	o to E14.	Don t know	9
	iny days of vaginal bleeding did you have?	Г	# of days
Go to E	14.		
E12. In the la	st 30 days, did you have heavy, gushing type bleeding	Yes	1
	s too much for your pads or tampons, even when changed	No	2
frequent	tly?	Refused	8
		Don't know	9
E13. In the la	st 30 days, have you passed blood clots that are	Yes	1
larger th	an a tablespoon?	No	2
		Refused	8
		Don't know	9
E14. During the	he last 30 days, did you have hot flashes?	Yes	1
		No	2
		Refused	8
		Don't know	9
E15. During the	he last 30 days, did you have night sweats?	Yes	1
		No	2
		Refused	8
		Don't know	9

F. SEXUAL ACTIVITY

Now I am going to ask you about sex.

- **F1.** In the last 30 days how many times did you have orgasms, either with intercourse or other than with intercourse?
- F2. In the last 30 days, how frequently did you experience pain deep inside during sex?
 (READ FIRST 5 CATEGORIES)

Most or all the time Some of the time A little of the time None of the time Not having sex **Refused Don't know**

of times
 · 1

•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	1
															-

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Monthly Telephone

Questionnaire

The next questions are about vaginal dryness, birth control pills and hormone medications.

F3. In the last 30 days, how frequently did you experience vaginal dryness?	Most or all the time Some of the time A little of the time None of the time Refused Don't know	1 2 3 4 8 9
F4. In the last 30 days, have you started or stopped using birth control pills, or switched to a different brand?	No Started Stopped Switched Refused Don't know	1 2 3 4 8 9
IF YES F5. What kind did you start using (or switch to)?		

F6. In the last 30 days, have you had Norplant, small rods with hormone inserted under your skin?	Yes No Refused Don't know	·····1 ·····2 ·····8 ·····9
F7. In the last 30 days, have you had injectables like Depo-Provera?	Yes No Refused	1 2 8

Don't know

Yes

No

Yes

No

Yes

No

Refused

Refused

Don't know

Don't know

Refused

Don't know

- F8. Have you used progesterone cream in the last 30 days?
 - **F9.** What dosage did you use?
- **F10.** In the last 30 days, have you taken hormone replacement therapy (HRT) such as Premerin or Prempro?
- **F11.** In the last 30 days, have you taken other hormone medications for any conditions such as infertility, endometriosis or polycycstic ovary disease?

IF YES

F12. What type of medication(s)

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Monthly Telephone Questionnaire

<u>G. STRESS</u> Now I am going to ask you about stress.

G1.	In the last 30 days, how hard was it for your family to pay for basic expenses like food, clothing, shelter, medical care and transportation?	No Problem Sometimes Difficult Moderately Difficult Very Difficult Refused Don't know	· · · · · · 1 · · · · · · 2 · · · · · · 3 · · · · · · · 4 · · · · · 8 · · · · · 9
G2.	In the last 30 days, how often did you forget to do important things?	Always A lot Some Rarely or never Refused Don't know	· · · · · · 1 · · · · · · 2 · · · · · · 3 · · · · · · 4 · · · · · 8 · · · · · 9
G3.	In the last 30 days, how often did you feel like you had more to do than you could get done?	Always A lot Some Rarely or never Refused Don't know	1 2 3 4 8 9
G4.	In the last 30 days, how often did you feel like you were at your limit like you couldn't handle another thing?	Always A lot Some Rarely or never Refused Don't know	· · · · · · 1 · · · · · 2 · · · · · · 3 · · · · · · 4 · · · · · 8 · · · · · 9
G5.	In the last 30 days, how often did you feel like important issues in your life were not under control?	Always A lot Some Rarely or never Refused Don't know	1 2 3 4 8 9
G6.	Now, please think about the two or three most stressful things in In the last 30 days, how often did you think about these things when you didn't want to?	your life. (pause) Always A lot Some Rarely or never Refused Don't know	1 2 3 4 8 9
G7.	In the last 30 days, how often did you try to avoid letting yourself get upset about these things?	Always A lot Some Rarely or never Refused Don't know	· · · · · · 1 · · · · · · 2 · · · · · · 3 · · · · · · 4 · · · · · 8 · · · · · 9

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FGS

Monthly Telephone Questionnaire

G8. In the last 30 days, how often did you have trouble falling asleep because of these things?

Always	 1
A lot	 2
Some	 3
Rarely or never	 4
Refused	 8
Don't know	 9

Time End: : AM PM

H. CLOSING REMARKS

The interview is now complete. Thank you very much for your time and effort. The information you provided will be very helpful in understanding fibroid growth. These updates will take about 15 minutes. We will continue calling monthly to find out about your symptoms and lifestyle then. Last time you indicated that ______ was convenient for you. Is that still the best time to reach you?

Thanks again. An interviewer will be calling you on (restate date and time). Do you have any questions before we end this call?

[If there are questions, respond to those as instructed in the interview procedure manual or as you were taught in the interview training.]

If no questions or after all questions are answered, 'Goodbye.'

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Monthly Telephone Questionnaire

I. INTERVIEWER'S REMARKS

H1. Respondent's cooperation was:

H2. The overall quality of this interview was:

Very Good 1 Good 2 Fair 3 Poor 4 Unsatisfactory1 Questionable 2 Generally Reliable 3 High Quality 4

H3. Place a check for any section for which the quality of the interview was particularly unsatisfactory or questionable

		Unsatisfactory	Questionable
SECTION B.	Occupational Data		
SECTION C.	Medical History		
SECTION D.	Physical Activity		
SECTION E.	Diet		
SECTION F.	Weight Questions		
SECTION G.	Smoking History		
SECTION H.	Pregnancy History		
SECTION I.	Menstruation		
SECTION J.	Sexual and Contraceptive History		
SECTION K.	Stress		
SECTION L.	Ethnicity, Education and Income		

H4. Comments