FGS _____ FGS FORM 100 VERSION: 051603 DATA ENTRY INTL.: _____

Initial Telephone Questionnaire

Participant ID:	FGS-			
Interviewer ID:				
Date of Interview:				
Length of Interview:		MONTH	DAY	YEAR Minutes
No. of Sessions:]
Outcome Code:				1











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i		
Time Began:	:	AM PM

A. INTRODUCTORY SCRIPT

This should be free form and includes the following sections:

- -Introduction
 - 1. Ask for the participant, identify yourself.
- -Reason for call
 - 1. Explain why you are calling.
 - 2. Tell how long it will take.
 - 3. Ask if she has time now.
- -Type of information you are asking
- 1. Explain the type of questions you will ask, making sure to mention that some of the information is very personal.
- -Explain her rights
 - 1. She is free to ask why we are asking any questions.
- 2. She does not have to answer any questions that make her feel uncomfortable--this will not affect her participation in the study itself.
- -Ask:
 - 1. If she has any questions before starting.
 - 2. If she could get a calendar to keep by the phone.
 - 3. If she has a record of her period, if she could get that as well.

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Sample Script:			
	and I am calling or may I speak with		
participation in the Fibroi	•	like to ask you question	_
[If not] , when would be a	better time to call?		
	e, diet, and sex. Because	<u> </u>	cycle, medical history, and the uterus, many of the
	er any questions if you fe This will not affect your pa	· ·	al or that you do not want to itself.
Feel free to ask question such questions.	s if you do not understand	I the question or would	d like to know why we ask
	ns right now? Could youns, and if you have a reco	_	

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B. OCCUPATIONAL HISTORY

The first questions are about your work.

B1.	Are you currently employed?	Yes No Refuse Don't k i			1
B2.	How many hours do you work per week as paid employn	nent?			Hours
В3.	During a typical day when you are working, do you most	Stand Walk Do heav	rier physical activinging, carrying, etc.) : (e.g. sit/stan		1
	C. MEDICAL HI	STORY			
C1.	What month and year were you first told by a health professional that you had uterine fibroids?	Mont	h Year		nown, fill es with 9's
		Write o	ut MONTH:		
C2.	Did you learn about your fibroids because they were investigating a problem you were having or were they for incidentally during a routine examination? Reason is more important than type of exam. For example, If response is "Pelvic Exam," probe with repeat of question for the type of exam they were found during.	und Normal Routine Uterine			1 3 4
C3.	At that time, how many fibroids were found? If number not known ask C3a			No. of Fibro	oids
	C3a. Did you have one or more than one fibroid at that time?	One More the Refused Don't k i	d		1 2 3
C4.	What was size the largest?	Size		Unit of	f measure

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Now I am going to ask you about your overall health and general feelings about your health. This series of questions has multiple choice answers. I will read the possible answers to you with each question.

C5.	Overall, how would you rate your health now?	Excellent / Very Good	1
		Good	 2
		Fair	 3
		Poor	 4
		Refused	 8
		Don't know	 9
C6.	How limited are your daily activities because of your health?	A lot	 1
	, ,	Some	 2
		A little	 3
		Not at all	 4
		Refused	 8
		Don't know	 9
C7.	How much daily discomfort do you have?	A lot	 1
	•	Some	 2
		A little	 3
		Not at all	 4
		Refused	 8
		Don't know	 9
C8.	Suppose you were told that you were going to spend the	Pleased or mostly satisfied	1
	rest of your life feeling just the way you have for the past	Mixed	 2
	month or so. Your symptoms would be no better or worse.	Mostly dissatisfied	 3
	Which of the following answers best describes how you	Very Dissatisfied	 4
	would feel about that?	Refused	 8
		Don't know	 9
C9.	To what extent, if at all, do you worry about your health?	A lot	 1
		Some	 2
		A little	 3
		Not at all	 4
		Refused	 8
		Don't know	 9

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The next questions are related to symptoms. Some of these are very personal and I would like to remind you that you may ask at any time why a question is being asked, and you don't have to answer any questions that make you feel uncomfortable.

C10. During the last 30 days, how much of a problem was vaginal bleeding (including menstruation) for you?	Big Medium Small None Refused Don't know	
C11. During the last 30 days, how much did vaginal bleeding interfere with your daily responsibilities, such as going to work/caring for family members, and doing housework?	A lot Some A little Not at all Refused Don't know	
C12. During the last 30 days how much did vaginal bleeding limit your social activities, such as visiting friends, taking vacations, and having company?	A lot Some A little Not at all Refused Don't know	
C13. During the last 30 days how much of the time have you felt excessively tired?	All or Most of the time Some of the time A little of the time None of the time Refused Don't know	1348
C14. During the last 30 days, how much of the time have you had back pain?	All or Most of the time Some of the time A little of the time None of the time Refused Don't know	1348
The next two questions ask you to recall the number of days.		
C15. During the last 30 days, about how many days did you have cramps, discomfort or pain the pelvic area?		No. of days
C16. During the last 30 days, about how many days did you have a feeling of heaviness in the pelvic area?		No. of days

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The next questions are multiple choice. Initial Telephone Questionnaire

C17.		e last 30 days, how much of a problem was pelvic , discomfort, or pain for you? Was it:	A big problem Medium Problem Small Problem No Problem Refused Don't know	
C18.	discomfort	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	
	C18 (a).	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	
	C18 (b).	IF YES: During the last 30 days, how many days did you because of pelvic discomfort or pain?	u stay home	No. of days
C19.	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	1348
C20.	Do you tal	ke laxatives, such as Metamucil, on a regular basis?	Yes No Refused Don't know	
	IF YES T C21.	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	
C22.		e last 30 days how much of the time had a lot of gas?	All or Most of the time Some of the time A little of the time None of the time Refused Don't know	1348

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C23.	During the	last 30 days how much of the time have you	All or Most of the time	1
	had stoma	ch aches or nausea?	Some of the time	 2
			A little of the time	 3
			None of the time	 4
			Refused	 8
			Don't know	 9
C24	During the	last 20 days have you ever had a uring last?	Van	4
C24.	During the	last 30 days have you ever had a urine leak?	Yes No	 1
			Refused	 2
			Don't know	 ٥٥
			DOIT CKNOW	 3
	IF YES TO	C24.		
	C25.	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
	C26.	Was it due to things like coughing, laughing,	Laughing, etc.	 1
		sneezing or lifting? Or was it just an uncontrolled	Uncontrolled	 2
		response?	Refused	 8
			Don't know	 9
C27.	During the	last 30 days, did you sometimes feel like you	Yes	 1
		urinate urgently, even though you had little or	No	 2
	no warning		Refused	 8
			Don't know	 9
	IF YES TO	C27.		
	C28.	How much of a problem was it?	A big problem	 1
			Medium Problem	 2
			Small Problem	 3
			No Problem	 4
			Refused	 8

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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. C29. In the last month, have you been scheduled to receive treatment (including surgery) for your fibroids? Yes No 2 Refused Don't know C30. If yes: What type of treatment is scheduled? Hysterectomy Myomectomy Embolization Other: Specify: Refused Don't know C31. If yes: Has a date of the surgery been set? Yes Nο Refused Don't know C32. If yes: What is the date of the surgery? Month Day Year Write out Month The next three questions are about infections. C33. In the last 30 days, have you had cold sores (fever sores, Yes 1 fever blisters)? No 2 Refused 8 Don't know 9 C34. In the last 30 days, have you had canker sores Yes

Nο

Refused

Don't know

(mouth sores or mouth ulcers)?

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C35.	In the last 30 days, have you had genital herpes sores or blisters?	Yes No Refused Don't know	
	D. PHYSICAL ACTIV	<u>VITY</u>	
	The next questions are about vigorous physical activity.		
D1.	Currently do you engage in vigorous recreational activities that increase your heart rate or make you sweat for at least 30 minutes at a time?	Yes No Refused Don't know	1289
	IF YES TO D1D2. How many times per week do you engage in vigorous recreational activity?		No. of times
	Now I'd like to ask you about time that you spend walking shopping, as well as recreational walking.	ງ to work, during lunch or	
D3.	During a typical day, how much time do: you spend walking? Between	Up to ½ hour ½ hour and an hour 1 hour and 1½ hour 1 ½ hour and 2 hours 2 and 2 ½ hours 2 ½ and 3 hours More than 3 hours Refused Don't know	1245678
	<u>E. DIET</u>		
	The next questions are about your current diet.		
E1.	How often do you eat red meat?	Daily 3-6 times per week 1-2 times per week Less than once a week Never Refused Don't know	12458

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E2.	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
		Refused Don't know		8 9
E3.	How often do you eat at fast food restaurants?	Daily 3-6 times per week 1-2 times per week Less than once a week Never Refused Don't know		12458
E4.	How often do you eat fried foods?	Daily 3-6 times per week 1-2 times per week Less than once a week Never Refused Don't know		123458
E5.	In the last 30 days, how many caffeinated beverages did you drink each day, each week, or over the month?	per month per week Refused Don't know	or	per day 8
E6.	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 Refused Don't know	or	per day 8
E7.	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
	IF YES TO E7			
	E8. How many days?	No. of days		8
		Don't know		9

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E9.	In any of t	he last 30 days, have you been on a diet?	Yes No Refused Don't know		
	IF YES TO) FQ			
	E9a.	In the last 30 days were you on any of the following types of diets?	Low calorie Low fat		
		You can choose one or more than one category	Low carbohydrate		
			Vegetarian		4
			High protein like the Atkins	Diet	
			Liquid diet like Slim Fast Other (please specify)		
			Other (please specify)		
			Potus ed.		
			Refused Don't know		
E10.	In the last	30 days, have you been taking diet pills for any reason?	Yes		′
			No		
			Refused Don't know	• • • • • • • • • • • • • • • • • • • •	
	IF YES TO) F10	Don't know		
	E11.	What type of diet pill did you take?			
		F. WEIGHT QUESTIONS			
	Now I am	going to ask you about your weight.			
F1.	Approxima	ately what was your weight at age 20?			
					lbs.
Ea	Approxima	ately what was your weight at age 30?			
ΓΖ.	Approxima	ately what was your weight at age 50?			lbs.
				<u> </u>	
F3.	What is yo	our current weight?			
					lbs.
ΕA	What was	the most you ever weighed? Don't count pregnancy.			
Г4.	what was	the most you ever weighed? Don't count pregnancy.			lbs.
F5.	What was	the least you ever weighed since the age of 20?			
					lbs.

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F6.	pounds or	lifetime, how many times have you lost 20 more and gained at least 20 pounds back? t normal weight change related to pregnancy.			# of times
	The next of	G. SMOKING HISTORY questions are about tobacco smoke.			
G1.	That is, ha one cigare	ever smoked cigarettes on a regular basis? ve you ever smoked at least tte a day for six months or more? o section H	Yes No Refused Don't know	(section H)	1 2 8
G2.		e did you first start smoking on a regular basis?			Age
G3.	Do you cui	rrently smoke even one cigarette per day?	Yes No Refused Don't know		1
	IF YES TO G3a.	G3 How many cigarettes per day?	NOTE: GO TO	G4	per day
	IF NO TO G3b.	G3 How old were you when you quit?			Age
	G3c.	On average, how many cigarettes did you smoke per day?			per day
G4.		years in total have you smoked, g away any times when you quit?			years
		H. PREGNANCY HISTORY			
	The next s	section of the interview concerns your pregnancy history.			
H1.	If answer is tublar preg live births.	ever been pregnant? s NO, clarify that pregnancy includes abortions, mancies, molar pregnancies, still births, as well as to section I	Yes No Refused Don't know	(Section I)	1 2 8

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H2.	How many deliveries have you had, including live births and still births?	Deliveries		
	If NONE, skip to section I If at least ONE, go to H3	Deliveries	i	
Н3.	When was the last time you gave birth?	Month Write Month	Year	
	Now I would like to find out more about your last delivery.			
H4.	How did your pregnancy end?	Live birth Still birth Multiple births SPECIFY OUTCOME:		1 2 3
	[IF STILLBORN, GO TO SECTION I]			
		REFUSED DON'T KNOW		8
Н5.	Was this baby born early, late or on time?	Early Late On Time Refused		1 2 3
	IF EARLY OR LATE	Don't know		9
	H6. How many weeks (early/late?)	# of weeks		
H7.	Did you have a C-section rather than a vaginal delivery? IF YES TO H7	Yes No Refused Don't know		1 2 8 9
	H8. Was the C-section done after or before you started labor?	After Before Refused Don't know		1 2 9

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Н9.	Was labor induced?	Yes No Refused Don't know		1 2 8
H10.	Were you given anything to make your contractions stronger?	Yes No Refused Don't know		1 2 8
H11.	Did you breastfeed this baby?	Yes No Refused Don't know		1
	IF YES TO H11			
	H12. How many months did you breastfeed this baby? By breastfeeding we mean nursing at least twice in a 24-hour period.	# Months	3	
	I. MENSTRUATION			
	The next questions are about menstrual periods.			
I1.	What was the beginning date of your most recent menstrual period? Please check your calendar. Take your time and be as accurate as possible.	Mont	h Day	Year
	'	WRITE MONTH	,	
	If the participant is currently having a period, also record the beginning date of the current period:			
		Monti WRITE MONTH	h Day	Year
I2.	IF LESS THAN TWO MONTHS SINCE MOST RECENT PERIOD CHECK HERE AND SKIP TO 14.			
13.	Are there reasons that you know of why you have not had menstrual period since [MONTH and YEAR from I1(if different from this year)]?			
14.	Thinking of your most recent period, how many days of bleeding did you have (don't count spotting)?	# of days		

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I5. 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+tampons/day 16. Do you use high absorbency pads or tampons on these days? Yes No 2 Refused Don't know 17. Are there additional methods that you need to use for bleeding. Yes 1 such as towels, Depends or cups? Nο Refused 8 Don't know 9 Now I have a question about spotting, very light bleeding-just spots of blood rather than real blood flow. 18. At the time of your last period, how many days of spotting, if any, did you have (READ CATEGORIES): Just before real blood flow? Just after real blood flow ended? 19. Thinking about the last 6 months, how often are you having menstrual periods? That is, how many days are there between the start of one period to the start of the next period? # of days OR If less than 20 days, probe: Too irregular to say 1 Was that the number of days between the start of one bleeding period to the start of the next bleeding period? **I10.** Did you have times when you had heavy, gushing type bleeding Yes 1 that was too much for your pads or tampons, even when Nο 2 changed frequently? Refused Don't know 9 **I11.** During the last 6 months, have you passed blood clots that were Yes 1 larger than a tablespoon? No Refused 8 Don't know 9 The next questions are about menopausal symptoms. **I12.** Has a health professional ever told you that you had Yes perimenopausal or menopausal symptoms? Nο Refused

Don't know

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Initial Telephone Questionnaire PATA ENTRY INTL.: ______ 113. During the last 30 days, did you have hot flashes? Yes

During the	last 30 days, did you have hot flashes?	Yes No Refused Don't know	1289
During the	last 30 days, did you have night sweats?	Yes No Refused Don't know	1 2 8
	J. SEXUAL AND CONTRACEPTIVE	/E HISTORY	
In the last	30 days, how many times did you have orgasms,	se?	88=REFUSED
			99=DON'T KNOW
		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	
The next of	questions are about vaginal dryness and birth con	trol pills.	
		Most or all the time Some of the time A little of the time None of the time Refused Don't know	
This also in		Yes No Refused Don't know	1 2 8
[IF YES] J5.	Do you currently take birth control pills?	Yes No Refused Don't know	1289
J6.	What type of birth control pills are you taking?		
	Now I am In the last either with The next of the last (READ FIII) Have you This also it [IF YES] J5.	Now I am going to ask you about sexual activity. In the last 30 days, how many times did you have orgasms, either with sexual intercourse or other than with sexual intercourse. In the last 30 days, how frequently did you experience pain deep inside during sex? The next questions are about vaginal dryness and birth continuous In the last 30 days how frequently did you experience vaginal dry (READ FIRST 4 CATEGORIES TO PATIENT) Have you ever used birth control pills? This also includes "progesterone only" pills ("POP") [IF YES] J5. Do you currently take birth control pills?	During the last 30 days, did you have night sweats? No Refused Don't know J. SEXUAL AND CONTRACEPTIVE HISTORY Now I am going to ask you about sexual activity. In the last 30 days, how many times did you have orgasms, either with sexual intercourse or other than with sexual intercourse? In the last 30 days, how frequently did you experience pain deep inside during sex? In the last 30 days, how frequently did you experience pain Some of the time A little of the time None of the time Non thaving sex Refused Don't know The next questions are about vaginal dryness and birth control pills. In the last 30 days how frequently did you experience vaginal dryness? (READ FIRST 4 CATEGORIES TO PATIENT) Most or all the time Some of the time A little of the time None of the time A little of the time None of the time Refused Don't know Have you ever used birth control pills? This also includes "progesterone only" pills ("POP") No Refused Don't know [IF YES] J5. Do you currently take birth control pills? Yes No Refused Don't know

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	J7.	What is the reason for taking them? (READ CATEGORIES)	Contraception Regulating your period Menopausal symptoms Other reasons Refused Don't know	 13489
J8.	Have you under you	ever had Norplant, small rods with hormone inserted r skin?	Yes No Refused Don't know	
	[IF YES] J9.	Are you still using Norplant?	Yes No Refused Don't know	
J10.	·	ever had injectables like Depo-Provera?	Yes No Refused Don't know	 1 2 8 9
	[IF YES] J11.	Are you still using injectables like Depo-Provera?	Yes No Refused Don't know	 1289
J12.	including s This might	ver take any medication or hormone shots, to help in getting pregnant? have been Clomid, Pergonal, hCG, tine or other drugs.	Yes No Refused Don't know	 2
J13.	[IF YES]	used progesterone cream in the last 30 days?	Yes No Refused Don't know	
J15.		What dosage did you use? The hormone replacement therapy (HRT) The remerin or Prempro?	Yes No Refused Don't know	 _

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Yes	 1
No	 2
Refused	

Don't know

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J16.	Are there other hormone medications for any conditions
	such as infertility, endometriosis or polycycstic ovary
	disease that you have taken or are taking now?

[IF YES]

J17. What type?

K. STRESS

Now I am going to ask about stress. These are multiple choice questions.

K1.	In the last 30 days, how hard was it for your family	No Problem	1
	to pay for basic expenses like food, clothing, shelter,	Sometimes Difficult	2
	medical care and transportation?	Moderately Difficult	3
	•	Very Difficult	
		Refused	
		Don't know	9
K2.	In the last 30 days, how often did you forget to do	Always	1
	important things?	A lot	2
		Some	3
		Rarely or never	4
		Refused	8
		Don't know	9
K3	In the last 30 days, how often did you feel like you had more	Always	1
110.	to do than you could get done?	A lot	
	to do than you oodid got done.	Some	
		Rarely or never	4
		Refused	8
		Don't know	9
		Don't know	
K4.	In the last 30 days, how often did you feel like you	Always	1
	were at your limit, like you couldn't handle another thing?	A lot	2
		Some	3
		Rarely or never	4
		Refused	8
		Don't know	9
K5	In the last 30 days, how often did you feel like important	Always	1
	issues in your life were not under control?	A lot	9
	Todado III your ino word not under contror:	Some	3
		Rarely or never	
		Refused	Ω
		Don't know	9
		DOIL KILOW	9

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Now, please think about the two or three most stressful things in your life. Have these things in mind when answering the next three questions.

K6. In the last 30 days, how often did you think about these

	things when you didn't want to?	A lot Some Rarely or never Refused Don't know		2 4 8
К7.	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		1348
K8.	In the last 30 days, how often did you have trouble falling asleep because of these things? L. ETHNICITY, EDUCATION	Always A lot Some Rarely or never Refused Don't know		1348
L1.	What is your current age?	AGE:		
L2.	What is your date of birth?	Month	Day	Year
L3.	Which category best describes your racial heritage? (YOU CAN CHOOSE MORE THAN ONE)	American Indian or Ala Asian or Pacific Islande Black White Other Specify: Refused Don't know	skan Native	1
L4.	Which category best describes your ethnicity?	Hispanic Origin Not of Hispanic Origin Refused Don't know		2

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L5.	What is your highest level of education?	Less than high school High school degree Some college or some tech	1 2
		beyond high school	3
		College degree College plus additional training	4
		but no other degree Post-graduate degree such as	5
		master's, Ph. D., MD or other	6
L6.	Including income provided by you, your husband or any other person in your household,	LESS THAN \$40,000 BETWEEN \$40,000 AND	1
	which range of incomes comes closest to your total household income before taxes for the past year?	\$60,000 BETWEEN \$60,000 AND \$100,000	2
		MORE THAN \$100,000	4
L7.	How many people, including yourself, were supported		
	by this income for the last year?	# PERSONS	
L8.	Are you curently [READ CATEGORIES]	SINGLE, NEVER MARRIED	1
		MARRIED, OR LIVING WITH	•
		SOMEONE AS MARRIED WIDOWED	2
		SEPARATED OR DIVORCED	4
L9.	During the last year, have you ever been without	_	1
	health insurance for a month or longer?		2
		DON'T KNOW	3
L10	Do you have health insurance now, including	YES	1
	Medicare or Medicaid, or coverage by someone		2
	else in your family?	DON'T KNOW	3
	[IF YES to L10.]		
	Which of the following types of insurance	public insurance (Medicare,	
	do you have now? [READ CATEGORIES]		1
			4
_12.	If you were unable to work for a month because of a medical	COVERED	1
	problem, do you have sick leave or disability that would cover	SOME LOSS OF INCOME	2
	you during that time, or would you lose your income during	LOSE ALL OR MOST	•
	such a time?	OF INCOME NOT CURRENTLY WORKING	3
		FOR INCOME	4
		Time End:	AM PM

FGS
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Initial Telephone Questionnaire

M. 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 lifestyle then. Last time you indicated that Is that still the best time to reach you?		
I would like to ask one more question before we end the call. How did you hear about the Fibroid Growth Study?	Physician/Nurse	
	Name:	
	Website	
	Bookmark	
	Radio	
	Word of mouth	

Other

Specify:

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/"

N. INTERVIEWER'S REMARKS

N1. Respondent's cooperation was:	Very Good Good Fair Poor	1 2 3 4
N2. The overall quality of this interview was:	Unsatisfactory Questionable Generally Reliable High Quality	1 2 3

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Initial Telephone Questionnaire

N3. 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		

N4.	<u>Comments</u>