

The UITN is supported by cooperative agreements from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in collaboration with the National Institute of Child Health and Human Development (NICHD)

	P PATIENT SURVEY 09/01/04 (A) Y INFORMATION FOR OFFICE USE ONLY:
A1. STUDY ID#: LABEL	A2. VISIT # 10 WEEKS
A3. DATE FORM DISTRIBUTED: / / / /	A4. STUDY STAFF INITIALS:
A5. MODE: SELF-ADMINISTERED	

Introduction: Thank you for agreeing to participate in the BE-DRI study.

We will ask you to complete a survey like this one at several time points in the study. This survey is called the Follow-Up Patient Survey Parts I & II and is completed at all post-intervention study visits. Part I contains measures of your current quality of life and an assessment of your capabilities in the performance of routine physical daily living activities. Part II includes questions about costs in your daily life that are related to your problem of incontinence.

As with all of the information we collect for this research study, all of your responses are completely confidential. Your responses are never linked with your name and your name never appears on any of the research documents. Providing this information will <u>not</u> affect any of your services, benefits, or eligibility for coverage.

Part I of the survey should take about 15 minutes to complete. Ideally, you will be able to complete the entire survey in one sitting.

There are five (5) parts to the entire Follow-Up Patient Survey. Please read the instructions at the start of each section carefully before you begin each new section.

Please complete this questionnaire at your earliest convenience and return it to the Study Nurse as soon as possible.

Try to answer every item, but do not dwell too long on any one question. We want <u>your</u> answers, so please complete the questionnaire on your own. After you have completed the Survey, please check to make sure you have not missed any items. If you have any questions about any of these items, please call me:

A6. What is the date that you are starting to fill out this Survey?

	/	/
Month	Day	Year

Section B: Quality of Life, Part I

This section asks for your views about your health. This information will help us keep track of how you feel and how well you are able to do your usual activities. These questions are about your health <u>now</u> and your <u>current</u> activities.

	Excellent	Very Good	Good	Fair	Poor
B1. In general, would you say your health is:	1	2	3	4	5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle one number for each activity)

		YES, I'm limited a lot	YES, I'm limited a little	NO, I'm not limited at all
B2.	Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
B3.	Climbing several flights of stairs	1	2	3

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>? **Circle one number for each activity.**

		YES	NO
B4.	Accomplished less than you would like	1	2
В5.	Were limited in the kind of work or other activities	1	2

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

Circle one number for each activity.

		YES	NO
B6. Acc	omplished less than you would like	1	2
B7. Didr	n't do work or other activities as carefully as usual	1	2

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	Not at all	Slightly	Moderately	Quite a bit	Extremely
B8. During the <u>past 4 weeks</u> , how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?	1	2	3	4	5

These questions ask about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>:

	All of the TimeMost of the TimeA		A Good Bit of the Time Some of the Time		A Little of the Time	None of the Time
B9have you felt calm and peaceful?	1	2	3	4	5	6
B10did you have a lot of energy?	1	2	3	4	5	6
B11have you felt downhearted and blue?	1	2	3	4	5	6

	All of the	Most of the	Some of the	A Little of the	None of the
	Time	Time	Time	Time	Time
B12. During the <u>past 4 weeks</u> , how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?	1	2	3	4	5

	Completely	Somewhat	Not At All
	Satisfied	Satisfied	Satisfied
B13. Since the intervention, how satisfied are you with your progress?	1	2	3

	Much Better	Better	About the Same	Worse	Much Worse
B14. Overall, do you feel that you are much better, better, about the same, worse, or much worse?	1	2	3	4	5

Section C: Quality of Life, Part II

These questions deal specifically with your accidental urine loss and / or prolapse. The symptoms in this section have been described by women who experience accidental urine loss and/or prolapse. Please indicate which symptoms you are now experiencing, and how bothersome they are for you. Be sure to circle an answer for all items.

GENERAL INSTRUCTIONS: Please read the first column of symptoms and circle "Yes" or "No" for each symptom. Then, for each question marked by a **"Yes"** answer, work across the page and tell us how bothersome that symptom is for you currently.

Do you currently experience			IF YES, Circle the one response below that best describes how bothersome that symptom is for you.				
	Yes	No	Not at all bothersome	Slightly bothersome	Moderately bothersome	Greatly bothersome	
C1frequent urination?	Yes 1	No 2	0	1	2	3	
C2a strong feeling of urgency to empty your bladder?	Yes 1	No 2	0	1	2	3	
C3urine leakage related to the feeling of urgency?	Yes	No 2	0	1	2	3	
C4urine leakage related to physical activity, coughing or sneezing?	Yes 1	No 2	0	1	2	3	
C5general urine leakage not related to urgency or activity?	Yes 1	No 2	0	1	2	3	
C6small amounts of urine leakage (that is, drops)?	Yes	No 2	0	1	2	3	
C7large amounts of urine leakage?	Yes	No 2	0	1	2	3	
C8nighttime urination?	Yes 1	No 2	0	1	2	3	

Affix ID Label Here

Do you currently experience				IF YES, Circle the one response below that best describes how bothersome that symptom is for you.				
Yes No				Not at all bothersome	Slightly bothersome	Moderately bothersome	Greatly bothersome	
C9bedwetting?	Yes	No 2		0	1	2	3	
C10difficulty emptying your bladder?	Yes	No 2		0	1	2	3	
C11a feeling of incomplete bladder emptying?	Yes	No 2		0	1	2	3	
C12lower abdominal pressure?	Yes 1	No 2		0	1	2	3	
C13pain when urinating?	Yes	No 2		0	1	2	3	
C14pain in the lower abdominal or genital area?	Yes	No 2		0	1	2	3	
C15heaviness or dullness in the pelvic area?	Yes 1	No 2		0	1	2	3	
C16a feeling of bulging or protrusion in the vaginal area?	Yes	No 2		0	1	2	3	
C17bulging or protrusion you can see in the vaginal area?	Yes	No 2		0	1	2	3	
C18pelvic discomfort when standing or physically exerting yourself?	Yes	No 2		0	1	2	3	
C19. Do you have to push on the vagina or perineum to empty your bladder?	Yes 1	No 2		0	1	2	3	
C20. Do you have to push on the vagina or perineum to have a bowel movement?	Yes 1	No 2		0	1	2	3	

C21. Do you experience any **other** symptoms related to accidental urine loss or prolapse? YES...... 1

NO...... 2 → SKIP TO C22

C21a. If yes, what is it (are they)?

C22. Please go back and review all of the symptoms in Section C above, items C1 - 21, and write below the one symptom that bothers you the most. For this item, please list **one** symptom only.

Some women find that accidental urine loss and / or prolapse affects their activities, relationships, and feelings. The questions in this section refer to areas in your life which may have been influenced or changed by your problem. For each question in this section, circle the one response that best describes how much your activities, relationships and feelings are being affected by urine leakage and / or prolapse.

To what extent has accidental urine loss and / or prolapse affected your

	Not at all	Slightly	Moderately	Greatly
C23ability to do household chores (cooking, housecleaning, laundry)?	0	1	2	3
C24ability to do usual maintenance or repair work done in home or yard?	0	1	2	3
C25shopping activities?	0	1	2	3
C26hobbies and pastime activities?	0	1	2	3
C27physical recreational activities such as walking, swimming, or other exercise?	0	1	2	3
C28 entertainment activities such as going to a movie or concert?	0	1	2	3

To what extent has accidental urine loss and / or prolapse affected your

	Not at all	Slightly	Moderately	Greatly
C29ability to travel by car or bus for distances less than 20 minutes away from home?	0	1	2	3
C30ability to travel by car or bus for distances greater than 20 minutes away from home?	0	1	2	3
C31going to places if you are not sure about available restrooms?	0	1	2	3
C32going on vacation?	0	1	2	3
C33church or temple attendance?	0	1	2	3
C34volunteer activities?	0	1	2	3
C35employment (work) outside the home?	0	1	2	3
C36having friends visit you in your home?	0	1	2	3
C37participation in social activities outside your home?	0	1	2	3
C38relationships with friends?	0	1	2	3
C39relationships with family excluding husband/companion?	0	1	2	3
C40ability to have sexual relations?	0	1	2	3
C41the way you dress?	0	1	2	3
C42emotional health?	0	1	2	3

To what extent has accidental urine loss and / or prolapse affected your

	Not at all	Slightly	Moderately	Greatly
C43physical health?	0	1	2	3
C44sleep?	0	1	2	3
C45. How much does fear of odor restrict your activities?	0	1	2	3
C46. How much does fear of embarrassment restrict your activities?	0	1	2	3

In addition, does your problem with accidental urine loss and / or prolapse cause you to experience

	Not at all	Slightly	Moderately	Greatly
C47nervousness or anxiety?	0	1	2	3
C48fear?	0	1	2	3
C49 frustration?	0	1	2	3
C50anger?	0	1	2	3
C51depression?	0	1	2	3
C52embarrassment?	0	1	2	3

Introduction: Part II of the Follow-Up Survey includes questions about costs in your daily life that are related to your problem of incontinence.

As with all of the information we collect for BE-DRI, all of your responses are completely confidential. Your responses are never linked with your name and your name never appears on any of the research documents. Providing this information will <u>not</u> affect any of your services, benefits, or eligibility for coverage.

Part II should take about 15 minutes to complete. Ideally, you will be able to complete the Survey in one sitting.

There are three (3) parts to Part II of the Follow-Up Survey. Please read the instructions at the start of each section carefully before you begin each new section. Try to answer every item, but do not dwell too long on any one question. We want <u>your</u> answers, so please try to complete the Survey on your own. After you have completed the Survey, please check to make sure you have not missed any items. If you have any questions about any of these items, please call me.

Section D: Incontinence Expenses

These questions are about expenses you may have because of your leakage of urine. Please answer each question for the number of supplies you use <u>in a typical week</u> to control your leakage of urine or additional laundry you do because of your leakage of urine. We are interested in things you do <u>specifically for your</u> <u>urine leakage</u>.

SUPPLIES USED

During a typical week, how many of each of these supplies do you use specifically for your urine leakage?

	Product	Number per week
D1.	Pantyliners or minipads	
D2.	Maxipads such as Kotex or Modess	
D3.	Incontinence Pads such as Serenity or Poise	
D4.	Diapers such as Depends or Attends	
D5.	Urethral pads such as Impress, Femassist	
D6.	Toilet paper - number of <u>changes</u>	
D7.	Paper towels - number of <u>sheets</u>	
D8.	Other	
	If other, describe:	

D9. During a typical week, how many loads of wash did you do specifically because of your urine leakage?

(Check one box only)

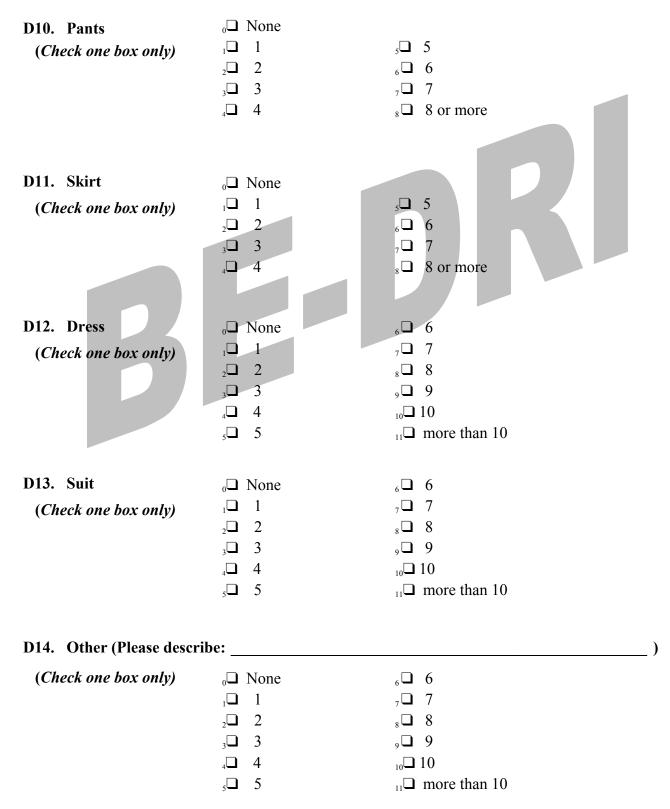
 $\begin{array}{c|c} {}_{0} \square & \text{None} \\ {}_{1} \square & 1 \\ {}_{2} \square & 2 \\ {}_{3} \square & 3 \end{array}$

₄**D** 4

- ₅□ 5 ₆□ 6
- $_{6} \square 0$
- $_{8}\square$ 8 or more

DRY CLEANING

During a typical week, how many items of clothing do you dry clean because of your urine leakage?



LOSS OF EMPLOYMENT AND VOLUNTEER WORK

- **D15.** Did your leakage of urine limit your years of employment or volunteer work?
 - $_{1}\Box$ Yes \checkmark

- $_{2}$ No \rightarrow SKIP TO SECTION E
- **D15a.** If yes, how old were you when you <u>stopped</u> your employment or volunteer work <u>because of</u> your urine leakage?

years old
D15b. What was your yearly salary when you stopped working?
\$

Section E: Matters of Health: The Health Utilities Index (HUI)

Instructions: This next section contains questions which ask about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, <u>during the past week</u>. To define the past week period, please think about the date this time 7 days ago and recall the major events that you have experienced during this period. Please focus your answers on your overall abilities, disabilities and how you felt during the past week.

You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.

Please read each question and consider your answers carefully. For each question, please select <u>one</u> answer that <u>best describes</u> your level of ability or disability <u>during the past week</u>. Please indicate the selected answer by <u>circling</u> the number beside the answer.

All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.

E1. Which <u>one</u> of the following best describes your ability, during the past week, to see well enough to read ordinary newsprint?

Able to see well enough without glasses or contact lenses	
Able to see well enough with glasses or contact lenses 2	
Unable to see well enough even with glasses or contact lenses 3	
Unable to see at all	

E2. Which <u>one</u> of the following best describes your ability, during the past week, to see well enough to recognize a friend on the other side of the street?

Able to see well enough without glasses or contact lenses	1
Able to see well enough with glasses or contact lenses	2
Unable to see well enough even with glasses or contact lenses	3
Unable to see at all	4

E3. Which <u>one</u> of the following best describes your ability, during the past week, to hear what was said in a group conversation with at least three other people?

	Able to hear what was said without a hearing aid 1
	Able to hear what was said with a hearing aid 2
	Unable to hear what was said even with a hearing aid
	Unable to hear what was said, but did not wear a hearing aid 4
	Unable to hear at all
E4.	Which <u>one</u> of the following best describes your ability, during the past week, to hear what was said in a conversation with one other person in a quiet room?
	Able to hear what was said without a hearing aid 1

	U				
Able to hear what was said with a hea	aring aid			2	
Unable to hear what was said even w	ith a heari	ng aid		3	
Unable to hear what was said, but did	l not wear	a hearin	g aid	4	
Unable to hear at all				5	

E5. Which <u>one</u> of the following best describes your ability, during the past week, to be understood, when speaking your own language with people who do not know you?

Able to be understood completely 1	
Able to be understood partially 2	
Unable to be understood 3	
Unable to speak at all 4	

E6. Which <u>one</u> of following best describes your ability, during the past week to be understood when speaking with people who know you well?

Able to be understood completely 1
Able to be understood partially 2
Unable to be understood
Unable to speak at all 4

E7. Which <u>one</u> of the following best describes how you have been feeling during the past week?

Happy and interested in life	1
Somewhat happy	2
Somewhat unhappy	3
Very unhappy	4
So unhappy that life was not worthwhile	5

E8. Which <u>one</u> of the following best describes the pain and discomfort you have experienced during the past week?

Free of pain and discomfort	1
Mild to moderate pain or discomfort that prevented no activities	2
Moderate pain or discomfort that prevented a few activities	3
Moderate to severe pain or discomfort that prevented some activities	4
Severe pain or discomfort that prevented most activities	5

E9. Which <u>one</u> of the following best describes your ability, during the past week, to walk? Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches or a walker.

Able to walk around the neighborhood without difficulty, and without walking equipment	1
Able to walk around the neighborhood with difficulty; but did not require walking equipment or the help of another person	2
Able to walk around the neighborhood with walking equipment, but without the help of another person	3
Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood	4
Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood	5
Unable to walk at all	6

E10. Which <u>one</u> of the following best describes your ability, during the past week, to use your hands and fingers?

Note: Special tools refers to hooks for buttoning clothes, gripping devices for opening jars or lifting small items, and other devices to compensate for limitations of hands or fingers.

Full use of two hands and ten fingers 1
Limitations in the use of hands or fingers, but did not require special tools or the help of another person
Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)
Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)
Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools)
Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

E11. Which one of the following best describes your ability, during the past week, to remember things?

Able to remember most things 1	
Somewhat forgetful 2	
Very forgetful	
Unable to remember anything at all 4	

E12. Which <u>one</u> of the following best describes your ability, during the past week, to think and solve day to day problems?

Able to think clearly and solve day to day problems	L
Had a little difficulty when trying to think and solve day to day problems	2
Had some difficulty when trying to think and solve day to day problems	3
Had great difficulty when trying to think and solve day to day problems	1
Unable to think or solve day to day problems	5

E13. Which one of the following best describes your ability, during the past week, to perform basic activities?

E14. Which one of the following best describes how you have been feeling during the past week?

Generally happy and free from worry	1
Occasionally fretful, angry, irritable, anxious or depressed.	2
Often fretful, angry, irritable, anxious or depressed	3
Almost always fretful, angry, irritable, anxious or depressed	4
Extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help.	5

E15. Which <u>one</u> of the following best describes the pain or discomfort you have experienced during the past week?

Free of pain and discomfort	1
Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities	2
Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities	3
Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief	4
Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities	5

- E16. Overall, how would you rate your health during the past week?
 - Excellent.
 1

 Very good.
 2

 Good.
 3

 Fair.
 4

 Poor.
 5
- E17. How did you complete the questionnaire? Please select the <u>one</u> answer that best describes your situation.?

By myself, without any help from anyone else 1	→ SKIP TO SECTION F
By myself, except someone else circled the answers on	
the questionnaire form for me	\rightarrow SKIP TO SECTION F
With the help of someone else	→ SKIP TO SECTION F
This questionnaire was completed by a family member, without help from the subject or patient	

E17a. If this questionnaire was completed <u>without help</u> from the subject or patient, who completed it?

Nurse or Other Health Professional...... 1 **V** SPECIFY TYPE OF HEALTH PROFESSIONAL

Section F: Matters of Money: Willingness to Pay

Please respond to these questions about how much money you would be willing to pay **out of your own pocket** for the treatments described. Assume that payments for these treatments are not covered by your health insurance or HMO, Medicare or Medicaid and that you must pay for them **out of your own pocket**.

F1. Imagine that a new treatment for incontinence becomes available that has no side effects. This new treatment reduces the number of times you *leak urine* by one quarter (25%).
For example, if you currently *leak urine* 4 times a day, with this new treatment you would *leak urine* only 3 three times a day. Or if you *leak urine* every day, this would be reduced to 3 days out of 4.

What is the most money that you would be willing to pay <u>per month</u> **out of your own pocket** for this treatment? (Check one box only)

ı Ģ \$5	₇ 🗖 \$75	
₂ □ \$10	s 🗖 \$100	
₃ 口 \$20	, , \$ 150	
4 □ \$30	10 \$200	
₅ □ \$40	u □ \$400	

F2. Imagine that a new treatment for incontinence becomes available that has no side effects. This new treatment reduces the number of times you *leak urine* by one half (50%).

For example, if you currently *leak urine* 4 times a day, with this new treatment you would *leak urine* only 2 times a day. Or if you currently *leak urine* every day, this would be reduced to 2 days out of 4.

What is the most money that you would be willing to pay <u>per month</u> **out of your own pocket** for this treatment? *(Check one box only)*

$_{0}\Box$ Nothing (I would not be willing to pay for this)	₀ □ \$50
1 3 5	₇ 🗖 \$75
₂ \$ 10	₈ 🗖 \$100
₃ □ \$20	₉ 🗖 \$150
₄ □ \$30	10 \$200
₅ □ \$40	11 400

F3. Imagine that a new treatment for incontinence becomes available that has no side effects. This new treatment reduces the number of times you <i>leak urine</i> three quarters (75%).		
For example, if you currently <i>leak urine</i> 4 times a day, with this new treatment you would <i>leak urine</i> only 1 time a day. Or if you <i>leak urine</i> every day, this would be reduced to 1 day out of 4.		
What is the most money that you would be willing to pay <u>per month</u> out of your own pocket for this treatment? <i>(Check one box only)</i>		
$_{0}$ Nothing (I would not be willing to pay for this) $_{6}$ \$50 $_{1}$ \$5 $_{7}$ \$75 $_{2}$ \$10 $_{8}$ \$100 $_{3}$ \$20 $_{9}$ \$150 $_{4}$ \$30 $_{10}$ \$200 $_{5}$ \$40 $_{11}$ \$400		
 F4. Imagine that a new treatment for incontinence becomes available that has no side effects. This new treatment cures your urine loss so that you do not leak urine. What is the most money that you would be willing to pay per month out of your own pocket for this treatment? (Check one box only) 		
$_0$ Nothing (I would not be willing to pay for this) $_6$ \$50 $_1$ \$5 $_7$ \$75 $_2$ \$10\$100		

- 3 □ \$20 4 □ \$30
- ₅**□ \$40**
- F5. Imagine that a new treatment becomes available that has no side effects. This new treatment reduces the number of times you *need to urinate* each day by one quarter (25%).

For example, if you currently *go to the bathroom* 16 times per day, with this new treatment you would only have to *go to the bathroom* 12 times per day.

₉ **□** \$150

₁₀ **** \$200

₁₁**□** \$400

What is the most money that you would be willing to pay <u>per month</u> **out of your own pocket** for this treatment? *(Check one box only)*

⁰ • Nothing (I would not be willing to pay for this)	₆ □ \$50
ı □ \$5	₇ 🗖 \$75
₂ □ \$10	₈ 🗖 \$100
₃ □ \$20	s150 🖵 و
₄ □ \$30	₁₀ \ \$200
₅ □ \$40	11 \ \$400

F6. Imagine that a new treatment becomes available that has no side effects. This new treatment reduces the number of times you <u>need to urinate</u> each day by one half (50%).		
For example, if you currently <i>go to the bathroom</i> 16 times per day, with this new treatment you would only have to <i>go to the bathroom</i> 8 times per day.		
What is the most money that you would be willing t treatment? <i>(Check one box only)</i>	o pay <u>per month</u> out of your own pocket for this	
Nothing (I would not be willing to pay for this $1 \bigcirc 5 $2 \bigcirc 10 $3 \bigcirc 20 $4 \bigcirc 30 $5 \bigcirc 40	s) $_{6} \square \$50$ $_{7} \square \$75$ $_{8} \square \$100$ $_{9} \square \$150$ $_{10} \square \$200$ $_{11} \square \$400$	
F7. Which of the following categories best represents your total personal income, including wages, social security, pensions, interest, dividends, etc. in the last year? (Check one box only)		
	s□ \$70,000-\$79,999	
	,□ \$80,000-\$89, 999 10□ \$90,000-\$99, 999	
	$_{10} = \$90,000-\$99,999$	
	$_{12}\square \$120,000-\$139,999$	
	ı₃❑ \$140,000-\$159, 999	
₀ □ \$50,000-\$59, 999	¹⁴ \$160,000 or more	
₇ □ \$60,000-\$69, 999	₁₃□ Don't know	

F8. Which of the following categories best represents the combined or <u>total</u> income of your <u>household</u> , including wages, social security, pensions, interest, dividends, etc. in the last year? (<i>Check one box only</i>)		
⁰ Less than \$5,000	₈ □ \$70,000-\$79,999	
ı □ \$5,000-\$9,999	₉ □ \$80,000-\$89, 999	
₂ □ \$10,000-\$19,999	10 □ \$90,000-\$99, 999	
₃ □ \$20,000-\$29,999	11 □ \$100,000-\$119, 999	
₄ □ \$30,000-\$39,999	12 □ \$120,000-\$139, 999	
₅ □ \$40,000-\$49, 999	13 □ \$140,000-\$159, 999	
₆ □ \$50,000-\$59, 999	14 □ \$160,000 or more	
₇ □ \$60,000-\$69, 999	₋₃❑ Don't know	