Script for MEPF Form 13
Quality of Life, Acceptability,and Cost

I have some questions about quality of life, acceptability of your medical treatment and cost. We want to know how acceptable the procedures during this study were to you, and the costs to you as a result of your miscarriage and being in this study. We will also be asking you about how much your miscarriage and medical treatment interfered with your usual activities, as well as feelings or emotions you have had during this time. You can complete the questionnaire by yourself or I can read the questions to you – whichever you would prefer. Should I read the questions to you or do you want to read them yourself and complete the form on your own?

MEPF

RCT ON THE MANAGEMENT OF EARLY PREGNANCY FAILURE
QUALITY OF LIFE, ACCEPTABILITY AND COST

Site			Patient No.			Letter Code		Visit	
								1	5

A. QUALITY OF LIFE

1. Visit date ___ ___ ___ - ___ ___ - 2 0 0 ___ (Month / Day / Year) FM13DT

1A. Questionnaire done (1) Yes (2) No QOL_DONE

IF NO, SKIP TO SECTION D ITEM 3.

2. Since you enrolled in the study, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

			None of the Time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
PHYTIME	A.	Cut down on the amount of time you spent on work or other activities	(1)	(2)	(3)	(4)	(5)	(6)
PHYACMPL	B.	Accomplished less than you would like	(1)	(2)	(3)	(4)	(5)	(6)
PHYKIND	C.	Were limited in the kind of work or other activities	(1)	(2)	(3)	(4)	(5)	(6)
PHYDFCLT	D.	Had difficulty performing the work or other activities	(1)	(2)	(3)	(4)	(5)	(6)

3. Since you enrolled in the study, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

			None of the Time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
EMTTIME	A.	Cut down on the amount of time you spent on work or other activities	(1)	(2)	(3)	(4)	(5)	(6)
EMTACMPL	B.	Accomplished less than you would like	(1)	(2)	(3)	(4)	(5)	(6)
EMTCARE	C.	Didn't do work or other activities as carefully as usual	(1)	(2)	(3)	(4)	(5)	(6)

4. The next questions ask about your social activities from the time you enrolled in the study until now.

A. To what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

(1) Not at all SOCINTF
(2) Slightly
(3) Moderately
(4) Quite a bit
(5) Extremely

B. Compared to your usual level of social activity, has your social activity decreased, stayed the same or increased because of a change in your physical or emotional condition?

(1) Much less socially active than before SOCLVL
(2) Somewhat less socially active than before
(3) About as socially active as before
(4) Somewhat more socially active than before
(5) Much more socially active than before

C. How often has your health limited your social activities (like visiting friends or close relatives?)

(1) None of the time SOCLMIT
(2) A little of the time
(3) Some of the time
(4) A good bit of the time
(5) Most of the time
(6) All of the time

D. Compared to others your age, are your social activities more or less limited because of physical health or emotional problems?

(1)` Much more limited than others SOCCOMP
(2) Somewhat more limited than others
(3) About the same as others
(4) Somewhat less limited than others
(5) Much less limited than others

5. The next questions are about any physical pain you may have experienced.

A. How much bodily pain have you had since you enrolled in the study?

BDLYPAIN

(1) None
(2) Very mild
(3) Mild
(4) Moderate
(5) Severe
(6) Very Severe

Since you enrolled in the study, how much has pain interfered with the following things?

			None of the Time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
PAINWORK	B.	Your normal work (including the work both outside the home and housework)	(1)	(2)	(3)	(4)	(5)	(6)
PAINMOOD	C.	Your mood	(1)	(2)	(3)	(4)	(5)	(6)
PAINMOVE	D.	Your ability to work or move about	(1)	(2)	(3)	(4)	(5)	(6)
PAINSLEP	E.	Your sleep	(1)	(2)	(3)	(4)	(5)	(6)
PAINPLAY	F.	Your recreational activities	(1)	(2)	(3)	(4)	(5)	(6)
PAINENJY	G.	Your enjoyment of life	(1)	(2)	(3)	(4)	(5)	(6)

6. From the time you enrolled in the study until now, how much of the time:

			None of the Time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
FULLLIFE	A.	Did you feel full of life?	(1)	(2)	(3)	(4)	(5)	(6)
LOTSENGY	B.	Did you have a lot of energy?	(1)	(2)	(3)	(4)	(5)	(6)
WORNOUT	C.	Did you feel worn out?	(1)	(2)	(3)	(4)	(5)	(6)
TIRED1	D.	Did you feel tired?	(1)	(2)	(3)	(4)	(5)	(6)
ENGHENGY	E.	Did you have enough energy to do the things you wanted to do?	(1)	(2)	(3)	(4)	(5)	(6)

7. From the time you enrolled in the study until now, how much of the time have you felt each of the following ways:

			None of the Time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
SAD	A.	I felt sad.	(1)	(2)	(3)	(4)	(5)	(6)
FAILED	B.	I felt I had failed as a person.	(1)	(2)	(3)	(4)	(5)	(6)
DISSATIS	C.	I felt dissatisfied with my life.	(1)	(2)	(3)	(4)	(5)	(6)
ALERT	D.	I felt mentally alert.	(1)	(2)	(3)	(4)	(5)	(6)
DISAPPNT	E.	I felt disappointed with myself.	(1)	(2)	(3)	(4)	(5)	(6)
CHEERFUL	F.	I felt cheerful	(1)	(2)	(3)	(4)	(5)	(6)
NOTWORTH	G.	I felt life wasn't worth living	(1)	(2)	(3)	(4)	(5)	(6)
SATISF	H.	I felt satisfied with my life.	(1)	(2)	(3)	(4)	(5)	(6)
HEALTHY	I.	I felt healthy.	(1)	(2)	(3)	(4)	(5)	(6)
CRYING	J.	I felt like crying	(1)	(2)	(3)	(4)	(5)	(6)
SUCCESS	K.	I felt I had been successful.	(1)	(2)	(3)	(4)	(5)	(6)
HAPPY	L.	I felt happy.	(1)	(2)	(3)	(4)	(5)	(6)
NODECIDE	M.	I felt I couldn't make decisions.	(1)	(2)	(3)	(4)	(5)	(6)
UNATTRAC	N.	I felt unattractive.	(1)	(2)	(3)	(4)	(5)	(6)
OPTIMIST	O.	I felt optimistic about the future.	(1)	(2)	(3)	(4)	(5)	(6)
REWARD	P.	I felt life was rewarding.	(1)	(2)	(3)	(4)	(5)	(6)
CHEERLES	Q.	I felt cheerless.	(1)	(2)	(3)	(4)	(5)	(6)
PURPOSE	R.	I felt life had a purpose.	(1)	(2)	(3)	(4)	(5)	(6)
TIRED2	S.	I felt too tired to do anything.	(1)	(2)	(3)	(4)	(5)	(6)
PLEASED	T.	I felt pleased with the way I am.	(1)	(2)	(3)	(4)	(5)	(6)
LETHARGC	U.	I felt lethargic.	(1)	(2)	(3)	(4)	(5)	(6)
EASYDEC	V.	I found it easy to make decisions.	(1)	(2)	(3)	(4)	(5)	(6)
ENJOY	W.	I felt life was enjoyable.	(1)	(2)	(3)	(4)	(5)	(6)
MNGLESS	X.	I felt life was meaningless.	(1)	(2)	(3)	(4)	(5)	(6)
RUNDOWN	Y.	I felt run down.	(1)	(2)	(3)	(4)	(5)	(6)

8. From the time you enrolled in the study until now, how much of the time have you experienced each of the following:

			None of the Time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
HARDWIND	A.	I found it hard to wind down.	(1)	(2)	(3)	(4)	(5)	(6)
HARDRELX	B.	I found it difficult to relax.	(1)	(2)	(3)	(4)	(5)	(6)
NERVENGY	C.	I felt that I was using a lot of nervous energy.	(1)	(2)	(3)	(4)	(5)	(6)
AGITATED	D.	I found myself getting agitated.	(1)	(2)	(3)	(4)	(5)	(6)
OVRREACT	E.	I tended to over-react to situations.	(1)	(2)	(3)	(4)	(5)	(6)
TOUCHY	F.	I felt that I was rather touchy.	(1)	(2)	(3)	(4)	(5)	(6)
INTOLRNT	G.	I was intolerant of anything that kept me from getting on with what I was doing.	(1)	(2)	(3)	(4)	(5)	(6)

B. ACCEPTABILITY

The next questions are about the medical treatment you had for your miscarriage.

		Totally Unacceptable	Somewhat Unacceptable	Neutral	Somewhat Acceptable	Totally Acceptable
PROCACPT	1. How acceptable was the procedure?	(1)	(2)	(3)	(4)	(5)
CRMPACPT	2. How acceptable was the cramping pain?	(1)	(2)	(3)	(4)	(5)
BLDACPT	3. How acceptable was the bleeding?	(1)	(2)	(3)	(4)	(5)
SIDEACPT	4. How acceptable were the side effects of the procedure?	(1)	(2)	(3)	(4)	(5)
DURACPT	5. How acceptable was the duration of the symptoms?	(1)	(2)	(3)	(4)	(5)
TIMEACPT	6. How acceptable was the time spent on treatment?	(1)	(2)	(3)	(4)	(5)

7. Overall, do you think the side effects of your treatment are: SETRTEXP

   Better than what you expected (1)
   About the same as expected (2)
   Worse than what you expected (3)

8. If someone you know has a miscarriage, would you recommend this procedure to her? RECOMEND

   Absolutely not (1)
   Probably not (2)
   Not sure (3)
   Probably yes (4)
   Absolutely yes (5)

9. If you ever had a miscarriage in the future, would you want the same type of treatment? DOAGAIN

   Absolutely not (1)
   Probably not (2)
   Not sure (3)
   Probably yes (4)
   Absolutely yes (5)

C. COST INFORMATION (FOR PERIOD AFTER YOU ENROLLED INTO THE STUDY)

1. Did you miss any days of school or work due to your miscarriage? (1) Yes (2) No MISSDAYS

IF YES, ANSWER A AND B.

	A Work	B School
How many days?	DAYSWORK __ __	__ __ DAYSSCHL

2. Has your illness required any members of your family or friends to help you out (either by taking care of you or by managing your household)? NEEDFHLP (1) Yes (2) No

IF YES, ANSWER A AND B

A. About how many hours total have family or friends spent in helping with your care? FHLPCAR3 _____ ____ ____ hours

B. How many hours total did they spend helping by caring for your children FHLPCHL3 _____ ____ ____ hours Not Applicable (1) FHLPCHNA

3. Were they required to take off time from work to assist you? FHLPOFF (1) Yes (2) No

IF YES, ANSWER A.

A. How much money total was lost to them for staying home? FHLPCOS4 $ _____ _____ _____ _____

4. Did you pay for someone to take care of you, your household or your children? PAIDHLP (1) Yes (2) No

IF YES, ANSWER A.

A. How much overall have you paid for the care? PHLPCOS4 $ _____ _____ _____ _____

5. How much of your time was spent at each doctor's visit for your miscarriage after you enrolled in the study?

A. Initial Visit ___ ___ Hours VIS1HRS
B. 2nd Visit ___ ___ Hours VIS2HRS
C. 3rd Visit ___ ___ Hours VIS3HRS
D. 4th Visit ___ ___ Hours VIS4HRS
E. 5th Visit ___ ___ Hours VIS5HRS

6. How much does it cost you every time when you come to the clinic, including transportation and parking? $ ___ ___ ___ VISCOST

7. How much did you pay for medicines you bought from the drug store? $ ___ ___ ___ MEDCOST

8. Can you think of any other costs associated with your miscarriage after you enrolled in the study? (1) Yes (2) No OTHRCOST

If Yes, Specify:

_____OCOST1SP_____ $ _____ OCOST1

_____OCOST2SP_____ $ _____ OCOST2

_____OCOST3SP_____ $ _____ OCOST3

_____OCOST4SP_____ $ _____ OCOST4

OFFICE USE ONLY

D. ADMINISTRATIVE MATTERS

1. Form completed by:
   - Patient (self-administered) (1) WHOCMPL
   - Staff Interview (2)

2. Language version:
   - English (1) LANGVER
   - Spanish (2)

GEN_CMNT

3. Comments:_____

CERT_SIG

4. Person completing or reviewing form: _____

   Staff Number: __ __ __ - __ __ __ CERT_NO

COMP_DT

5.. Date form completed: ___ ___ ___ - ___ ___ - 2 0 0 ___
   Month Day Year