

April 30, 1999

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Center: _____

Patient Initials: _____, _____

Rand Number: _____

Form
completed by: _____**A. VISIT INFORMATION****E_VISIT**1. Visit: ₀₀ Pre-Randomization ₁₂ 12M ₂₄ 24M ₃₆ 36M ₉₉ Other

2. Date of gynecologic examination: _____ / _____ / _____

Month Day Year

Recorded as E_EXAMDY = days from randomization to date of GYN exam

3. Was this examination performed at the study clinic? **E_VISLOC**Y₁ N₃4. Were any gynecological abnormalities referred for follow up? **E_GYNABN**Y₁ N₃*If Yes, answer a. through e. and complete a separate W18 for each abnormality. If no abnormalities skip to section B.*

a. Breast Exam

Y₁ N₃

b. Mammogram

Y₁ N₃

c. Pelvic Exam

Y₁ N₃**E_BABN****E_MABN****E_PABN**

d. Pap Smear

Y₁ N₃

e. Endometrial

Y₁ N₃**E_SABN****E_EABN****B. BREAST EXAM** (required annually)

Record clinical exam notes on back of form.

LEFT BREAST**RIGHT BREAST**

1. Exam performed?

Y₁ N₃ **deleted**Y₁ N₃ **deleted**Recorded E_BEXAM = either
or both left or right breast
exam done*If Yes, answer questions a. through d. If No, skip to section C*

a. Nipple discharge?

₁ No
₃ Yes, probably benign
₅ Yes, possibly malignant₁ No
₃ Yes, probably benign
₅ Yes, possibly malignant

b. Skin involvement?

₁ No
₃ Yes, probably benign
₅ Yes, possibly malignant₁ No
₃ Yes, probably benign
₅ Yes, possibly malignant

c. Axillary mass?

₁ No
₃ Yes, probably benign
₅ Yes, possibly malignant₁ No
₃ Yes, probably benign
₅ Yes, possibly malignantd. Breast mass (or
nodules)?₁ No
₃ Yes, probably benign
₅ Yes, possibly malignant₁ No
₃ Yes, probably benign
₅ Yes, possibly malignant

Recorded E_BEXRES = max result from questions a-d above

If breast mass, answer 1) through 3). If no breast mass, skip to section C

1) more than one mass? Y₁ N₃ ~~deleted~~ Y₁ N₃ ~~deleted~~

2) primary mass Y₁ N₃ ~~deleted~~ Y₁ N₃ ~~deleted~~
mobile?

3) size of primary mass: ₁ < 1 cm ₁ < 1 cm
 ₃ 1-3 cm ~~deleted~~ ₃ 1-3 cm ~~deleted~~
 ₅ > 3 cm ₅ > 3 cm

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C. MAMMOGRAM (required annually) Record clinical exam notes on back of form.1. Was a mammogram performed? **E_MEXAM**Y₁ N₃*If Yes, answer a. and b. If No, skip to section D*a. Date of mammogram: **Recoded E_MEXDY = days since randomization**____/____/____
Month Day Year

b. Results of the mammogram (check one for each breast):

Not Done

Incomplete

Normal

Benign

Probable benign finding

Suspicious finding

Malignant/Highly suggestive

LEFT BREAST

RIGHT BREAST

 X X I I N N B B P P S S M M**Question C1b recoded as E_MAMRES = the most serious result on either left or right breast****D. PELVIC EXAMINATION** (required annually) Record clinical exam notes on back of form.1. Was pelvic exam performed? **E_PEXAM**Y₁ N₃*If Yes, answer a. through c. If No, skip to section E* **E_PVULAB (Question D1a)**a. Any vulvar abnormality? ₁ No ₃ Yes, probably benign ₅ Yes, possibly malignant

1) If Yes, specify:

deleted _____b. Uterus Present? **E_PUTER**Y₁ N₃*If Yes, answer 1) and 2). If No, skip to question c.*1) Normal uterus size? **E_PUTSZ2** **E_PUTABN (Question D1b2)**Y₁ N₃2) Uterine abnormality? ₁ No ₃ Yes, probably benign ₅ Yes, possibly malignant

a) If Yes, specify:

deleted _____c. Could adnexae be palpated? **E_PADNEX**Y₁ N₃1) If yes, abnormality? **E_PADNAB**Y₁ N₃

a) If Yes, specify:

deleted _____

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E. PAP SMEAR (*recommended annually*)*Record clinical exam notes on back of form.*1. Was Pap smear done? **deleted**Y₁ N₃*If Yes, answer a. through c. If No, skip to section F.*a. Was Pap smear done at the study clinic? **deleted**Y₁ N₃b. Date sample collected: **deleted**____/____/____
Month Day Yearc. Result of Pap smear (*check 1 of the 4 choices below*) **deleted**₁ Cervix not present₃ Endocervical cells not seen. If so, 1) abnormal Pap smear in past 3 years?Y₁ N₃₅ Pap smear normal₇ Pap smear abnormal *If abnormal, answer questions 2) through 4)*

2) Atypical squamous (or glandular) cells of uncertain significance?

Y₁ N₃**deleted**3) Dysplasia? (*if yes, answer a) and b)* **deleted**Y₁ N₃

a) severity:

₁ Mild, atypia₃ Moderate₅ Severe**deleted**

b) Grade SIL

₁ Low₃ Medium₅ High**deleted**4) Cancer? **deleted**Y₁ N₃**F. ENDOMETRIAL ASPIRATION** (*performed for clinical indications*)*Record clinical exam notes on back of form.*1. Was endometrial aspiration performed? **deleted**Y₁ N₃*If Yes, answer a. through d. If No leave a. through d. blank.*a. Date sample collected: **deleted**____/____/____
Month Day Yearb. Was aspiration performed because of bleeding? **deleted**Y₁ N₃c. Results of aspiration (check one): **deleted**₀₅ No endometrial tissue identified₁₀ Cystic (simple) hyperplasia with atypia₁₅ Insufficient specimen₂₀ Adenomatous (complex) hyperplasia present₂₅ Normal atrophic endometrium₃₀ Adenomatous (complex) hyperplasia with atypia₃₅ Normal secretory endometrium₄₀ Atypia present₄₅ Normal proliferative endometrium₅₀ Cancer present

₅₅ Cystic (simple) hyperplasia present ₉₉ Other

d. If results are Other, specify:

~~deleted~~ _____

Variables in Section E dropped because of small sizes. There were a small number of women at each visit who had an endometrial aspiration so little information is lost.