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TITLE: Comparison of Norethindrone-Containing OCPs to Desogestrel OCPs and Depo-Provera in Women

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FOREWORD

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INTRODUCTION

This prospective longitudinal study examines contraceptive outcomes among active-duty military and civilian women who receive one of three different methods of contraception (Depo-Provera, Ortho Novum 1/35, and OrthoCept). Four hundred and fifty women aged 18-33 years are being recruited with 150 subjects in each condition. Military (Wilford Hall Medical Center) and civilian (The University of Texas Medical Branch at Galveston) recruitment sites each furnish 75 subjects per contraceptive condition. Subjects choose either oral or injectable contraception; however, those who select pills are randomly assigned to receive one of the two formulations under study. Participants are assessed at recruitment, and after 6, 12, 18, & 24 months of contraceptive use. At the initial visit, subjects complete a medical evaluation and physical examination as well as complete standardized self-report measures of health status, dysmenorrhea, and menstrual pain. In addition, bone density measurements using dual X-ray absorptiometry (DEXA) are completed and an evaluation of lipid levels is obtained. At each follow-up visit, subjects complete self-report measures of health status, dysmenorrhea, medical side effects, contraceptive satisfaction, as well as return completed menstrual calendars. Physical examinations are performed by a nurse practitioner or physician after 12 and 24 months of continuous contraceptive use and lipid levels are evaluated at these visits. Finally, another bone density measurement occurs after 24 months of contraceptive use. The specific technical objectives of this study are to determine at the conclusion of 2 years which of these three measures:

1. has the highest rate of continuation;
2. has the highest level of user satisfaction;
3. most effectively reduces the occurrence and severity of dysmenorrhea;

4. most effectively decreases the number of bleeding days per 90 day reference period;
5. has the lowest user failure rate resulting in pregnancy;
6. minimizes bone-density loss;
7. minimizes changes in lipo protein levels; and
8. minimizes the occurrence of medical side effects.

Collected data will be analyzed using repeated measure multi-variance statistical tests so that (1) trends and outcomes over 24 months of contraceptive use can be examined; (2) comparisons of outcomes of specific points in time (6, 12, & 24 months) may be performed; and (3) main effects of method, time, recruitment site, and their interactions can be evaluated. The broad aim of this proposal is to provide critical data on contraceptive outcomes that may be used to generate reproductive health care guidelines for servicewomen who have varying needs depending upon their military assignment.

This first summary report details the specific activities that have occurred during Year 1 of funding (September 23, 1996 through September 22, 1997). According to our Statement of Work, 4 major objectives and related tasks were to be completed during these first 12 months. These objectives are (1) implement the study protocol; (2) initiate recruitment of 3 contraceptive cohorts that will consist of 150 participants by Year 2 (75 from each site); (3) complete required medical assessments, laboratory tests, and self-report and satisfaction measures at each visit; and (4) analyze study data. We report on the progress of each objective by addressing all related tasks.

BODY

Objective 1: Implement the study protocol

Six specific tasks to be accomplished during the first five months of implementation were set forth in the original proposal to meet this objective. These tasks included: 1) refining the medical visit and contraceptive scripts; 2) standardizing the methodology and data collection instruments; 3) hiring required personnel; 4) initiating and completing protocol training at both sites; 5) developing reporting mechanisms between the two clinic sites; and 6) pilot testing self-report scannable forms.

Task 1. Outline for the initial and each follow-up visit has been developed using a checklist format (see Appendix A). Written scripts that are used by research personnel for recruitment, initial, and all subsequent medical visits have also been developed. These visit-specific checklists and scripts have been developed to insure integrity in the delivered protocol. This activity took approximately 2 ½ months to complete. As we move forward in this longitudinal study, refinements to the 6, 12, 18, & 24-month visit checklists and contraceptive scripts will be made as needed. Although a few unavoidable differences do exist between sites (medical forms and routine testing for sexually transmitted diseases), development of specific protocols to be followed at each site have kept differences to a minimum.

Task 2. Self-report instruments were developed for use in this study once official HURRAD and U. S. Surgeon General IRB approvals were received. Although preliminary drafts of questionnaires were included in the proposal, specific questions to assess contraceptive outcomes were carefully reviewed. We screened and identified the most relevant questions by careful review of the medical outcomes literature. Four distinct customized questionnaire packets (initial visit only, all visit, follow-up visits, nurse assessment) were then designed and

sent to National Computing Services for production on scannable paper (packets are included in Appendix B). This process took 4 months to complete; questionnaires were in place by mid April. A decision was made to not use scannable calendars to collect 90-day bleeding patterns because of the difficulty associated with data manipulation. Instead, subjects record their bleeding history on hand written calendars that are reviewed by research personnel. Data on bleeding patterns are then extracted using standardized definitions and recorded in pre-set grids on scannable forms. Finally, a 10-item questionnaire was developed to assess ongoing contraceptive practices, medical side effects, and satisfaction among those subjects who discontinue their chosen method of contraception.

Task 3. We have had some turn-over in grant-funded personnel at both UTMB and WHMC. At UTMB, the nurse practitioner who started 4 March 1997 resigned her grant-funded position on 18 June. However, the department of Obstetrics & Gynecology provided clinical support to recruit subjects and to follow enrolled participants until a replacement could be identified. On 25 August, 1997 the nurse practitioner position was filled for this site. The nurse practitioner assigned to WHMC tendered her resignation on 22 July, 1997 due to family constraints. However, no follow-up visits were missed as she remained on duty part-time through 10 September, 1997. Since this date, the Military PI has provided follow-up care to existing subjects. A licensed physician assistant who is WHMC credentialed has been successfully recruited and will begin her grant-funded activities on 3 November, 1997. In addition, a research assistant has been hired for each site to assist with recruitment. These research assistants will also be in place by 3 November, 1997. As the grant only provided funds for three employees, the department of Obstetrics & Gynecology has generously agreed to

provide additional funds to defray the cost of this fourth position. This extra employee will be assigned to WHMC to assist with the successful recruitment of our active-duty cohort.

Task 4. Protocol training for medical visits and data collection activities was completed at both sites via phone and electronic communication. Because the initial nurse practitioners at UTMB and WHMC had extensive experience with gynecologic concerns and family planning, this task was easily completed. Both practitioners reviewed recruitment and initial visit scripts. Revisions and changes were made according to site-specific hospital standard of care. The project director completed subsequent training of the currently employed nurse practitioner at UTMB in early September. Weekly meetings with the project director and primary investigator continue to occur. The project director and Military PI will commence training of the newly hired employees at WHMC on 3 November, 1997.

Task 5. Several lines of communication have been established between WHMC and UTMB. In April of 1997, weekly phone conferences were initiated between study personnel at both sites to maximize recruitment efforts as well as to troubleshoot any difficulties in protocol implementation. Further, electronic communications (email) were established in early May to expedite the sharing of information. Communications among the PI, Military PI, and Project Director occurred very frequently during the initial six months. To date, weekly communications among these individuals occur to problem-solve and review task objectives.

Task 6. We have acquired the software and machine to program the scanner to read self-report measures and are in the process of completing the four programs that will read each packet. Since we have previous experience with this software, we do not foresee having difficulty with this task.

Objective 2: Initiate recruitment of 3 contraceptive cohorts that will consist of 150 participants by Year 2 (75 from each site)

This objective contains five tasks that were to be initiated during the first 12 months of grant activity. These include: 1) recruit and obtain informed, written consent from 225 participants; 2) insure that each ethnic population is adequately represented at UTMB; 3) complete initial medical examination and history; 4) complete initial self-report measures for all participants and instructions for completing menstrual calendars; and 5) collect and conduct data entry of demographic data required for subject tracking. Substantial progress has been made in each of these areas.

Task 1. As of 10 October 1997, 67 subjects have been enrolled at UTMB and 23 active-duty women have been recruited at WHMC. Each subject has provided written informed consent using and all are seeking contraceptive services. Twenty-nine women have chosen Depo-Provera and 61 birth control pills with 28 woman randomly assigned to Ortho Novum 1/35 and 33 to OrthoCept. We originally projected enrollment to be 225 at both sites by 30 September. Therefore, the recruitment of our cohort in a timely manner is currently our highest priority.

Overall, recruitment of subjects at both UTMB and WHMC has been more difficult than forecasted. Although the reasons for this difficulty are different between the military and civilian sites, there is one commonality. Most women between the ages of 18 and 33 years who are interested in preventing pregnancy are either already using some type of prescription method of contraception or have used a method in the recent past, especially at WHMC. Our original protocol stipulated that women would only be eligible to participate in the current study if they had not taken birth control pills for 3 or more months or Depo Provera within the last year.

These criteria eliminated many potential subjects, especially at WHMC, and were identified as a significant barrier to subject recruitment. Upon careful review of the literature, we determined that shortening the time off hormonal contraception would not affect accurate measurements of desired outcomes. Therefore, we initiated conversation with our scientific officer on 23 May, 1997 and on 23 June, 1997 officially requested modification of these exclusion criteria to allow women who have been free from taking birth control pills in the last 30 days or have not had Depo Provera within 6 months to be eligible to participate. Although we have institutional approval for these changes at both UTMB and WHMC, final HURRAD approval has not been received. Our scientific officer believes that this modification will be approved in the immediate future. We expect these modifications to greatly improve our ability to recruit potential subjects at both sites, especially at WHMC.

At UTMB, another unforeseen barrier to subject recruitment also became evident. Our initial projections of women seeking contraception at UTMB suggested that our entire cohort could be recruit from patients seeking care through maternal and child clinics located in Galveston. Unfortunately, many women seeking care at this site are in excess of the weight requirements set forth by military standards or have not received a high school diploma or its equivalent. Thus, these potential subjects would not be representative of either new military recruits or reserves. We have implemented several strategies to improve our ability to recruit potential subjects. First, we established a satellite clinic in Webster, Texas where women in the greater Houston area could be seen. Second, we placed 6 separate advertisements in local newspapers and secured approximately 100 flyers soliciting participation were placed in high traffic locations (e.g., grocery stores, apartment complexes). Third, after receiving UTMB institutional approval, bi-monthly electronic solicitation (email posting) via the hospital

information services was initiated. Each of these preliminary strategies has improved recruitment. Fourth, in April of 1997 we contacted a nationally recognized marketing firm and obtained mailing labels of 9,632 women, 18 to 33 years who were Caucasian or African-American and lived within 20 miles of the two sites where women could be seen. After receiving institutional approval, 2,000 randomly selected mailing labels were placed on envelopes with a flyer soliciting participation. This technique has typically resulted in an enrollment of 1.5% of total flyers sent. Currently, we are mailing 500 solicitations every two weeks. Because of the success of this strategy we have also secured mailing labels of enrolled college women at three local colleges. Mailings to this population will be instituted within the next two weeks. Other strategies that have been helpful include rounding on the post-partum hospital ward, talking to potential subjects who are seen for prenatal care in our clinical care settings, and speaking to those women who are seen privately by gynecology faculty members.

Recruitment at WHMC has also been hampered because per WHMC regulations we are unable to provide monetary compensation to enrolled subjects. In addition, we were not able to start enrolling subjects until late April because the WHMC nurse practitioner was not a credentialed at WHMC despite her prior military assignment as a nurse at this setting. Therefore, we were required to wait approximately 4 weeks until she was officially credentialed before subject enrollment could take place. In order to meet recruitment objectives at this site, several strategies were developed. These include attending the bimonthly orientation meeting of newly arrived personnel; electronic broadcasts on WHMC informational systems; inservice education to other gynecology-based providers; and advertisements in military papers and posters. We obtained 2 subjects in May , 8 in June, and 15 in July demonstrating increased success. Additionally, we have requested institutional approval at WHMC to conduct direct

mail solicitation of active-duty women and will likewise obtain permission to do this at other military installations in the San Antonio area. Finally, the department of Obstetric & Gynecology at UTMB has agreed to support a full-time research assistant to be stationed at WHMC to help with recruitment of our initial cohort. We believe that this additional personnel will facilitate our ability to begin direct mail solicitation at other military installations and therefore, will substantially improve our abilities to successfully recruit potential subjects. As of this writing, we have hired a research assistant who will begin on 3 November 1997.

Task 2. The percentages of UTMB subjects recruited from each race/ethnicity by contraceptive condition is presented below. In order to mirror the race/ethnicity of active duty military women, 23 (31%) African-American, 4 (5%) Mexican-American , and 48 (64%) Caucasian women are needed in each of the three contraceptive conditions. We are currently monitoring the ethnicity of subjects recruited into this study to ensure that they ultimately approximate the ethnicity of women serving in the armed forces.

	Ortho Novum 1/35 % (n)	OrthoCept % (n)	Depo Provera % (n)
African-American	9 (2)	19 (5)	6 (1)
Mexican-American	14 (3)	11 (3)	0 (0)
Caucasian	77 (17)	70 (17)	94 (16)

Task 3. All recruited subjects have completed an initial medical examination and provided a thorough history, including past contraceptive practices and menstrual history. Each subject was screened for pregnancy and other potential health risks that would preclude the use of hormonal contraception.

Task 4. All recruited subjects have completed their self-report measures and have received instructions for completing menstrual calendars. The self-report questionnaires take 30–45 minutes to complete. All forms are reviewed by project personnel so that missing or inconsistent information can be addressed.

Task 5. Electronic databases has been developed to monitor recruitment (eligibility and recruitment strategies used) tracking (demographics and appointments) and contraceptive discontinuation. These databases contain information necessary to successfully contact subjects about future appointments, and monitor race/ethnicity of contraceptive condition, contraceptive discontinuation, and success of various recruitment efforts. All databases are linked to a mechanism for automatic data monitoring that will provide a hard copy of results, as needed.

Objective 3: Complete required follow-up medical assessments laboratory tests, and self-report and satisfaction measures at each visit

Activities associated with this objective are designed to maintain the research cohort. Although 10 tasks are associated with achieving this objective, only six are relevant to this summary report. These are: 1) order, prepare, and Xerox required study forms, and appointment reminder post cards; 2) prepare and mail appointment reminder postcards to each participant; 3) perform tracking procedures on participants whose appointment reminder cards were returned undelivered; 4) compensate subjects for their participation in the study at each follow-up visit and contact via phone all discontinuers; 5) dispense oral contraceptives or administer Depo-Provera and count unused or missed birth control pills; and 6) complete brief medical visit and satisfaction/side-effect measures at the 3-month follow-up visit. Each of these tasks has been accomplished for the 24 subjects at UTMB and 23 subjects at WHMC who completed the 3-month follow-up visit.

Task 1. As mentioned above, a system has been established to electronically monitor all follow-up visits and create reminder letters.

Task 2. At the conclusion of each subject's initial visit, she is provided with an appointment for her next follow-up visit. A reminder letter is generated from our electronic database 14 days prior to her appointment. Each subject is also called one day before her scheduled appointment as a reminder.

Task 3. Tracking procedures were implemented were employed on one subject who missed her 3-month follow-up appointment. Phone contacts were used to assist in locating this subject. At this time, no reminder letters have been returned as undeliverable.

Task 4. All subjects at UTMB have received compensation for their 3-month follow-up visit. Subjects recruited at WHMC cannot receive compensation per installation policy. At this time, 2 subjects at UTMB have discontinued their chosen contraceptive method and will be contacted by phone to complete the discontinuation assessment. No subject at WHMC has discontinued her contraception.

Task 5. At the initial visit, all women assigned to either pill condition receive a four month supply of pills, and are told to initiate use the Sunday after the start of their period. At the 3-month follow-up visit, another 3 pill packs are provided. During the reminder phone call about appointment time, pill users are also asked to bring in their pill packs. Each pill package has been numbered with the month it is to be used, and counts of all missed pills are recorded on the Nursing Assessment scannable form. With regard to Depo-Provera users, subjects have returned to clinic to receive their injection after the start of their period. These subjects are scheduled for an injection 104 days after their initial injection. To date, all subjects using this birth control method have maintained this scheduled.

Task 6. All subjects attended who their 3-month follow-up completed a brief medical visit to determine whether any medical problems have been encountered during this period. A structured interview using a scannable form was developed to accurately evaluate the occurrence and resolution of common medical side effects. This is completed by the medical provider at each visit. All subjects then complete the remaining self-report measures prior to leaving clinic. This return visit is usually much shorter, taking an average of 1 hour.

Objective 4: Analyze study data

This objective involves quantifying study results. There were 5 tasks identified for this objective that are relevant to this first 12 months: 1) develop and pilot database for collected data; 2) develop and finalize accuracy of importing menstrual calendar and related self-report questionnaires for database; 3) conduct reliability analysis on 10% of medical visits; 4) perform all data entry and verification of study data; and 5) reconcile out-of range and inconsistent data elements to insure accuracy of study data.

Task 1. As mentioned, we are in the process of completing the four computer programs to read each customized packet. All scanning will be completed at UTMB.

Task 2. As mentioned, menstrual calendars were not formatted to be read by the electronic scanner. Instead, handwritten calendars are being completed by subjects. These data are then coded by the research nurse using standardized definitions to assess number of bleeding runs, length of each bleeding run, number of nonbleeding intervals, length of nonbleeding run, number of spotting days, longest bleeding run, and longest nonbleeding interval. These collapsed data are then coded on a scannable form.

Task 3. We are currently in the process of conducting reliability analysis on 10 % of medical visits. These analyses will be ongoing for the remainder of the grant.

Task 4. All self-report measures completed at the initial visit are being reviewed to verify that all requested information has been completed. Missing data are flagged and the subject is contacted to obtain this information.

Task 5. All forms are being visually inspected of completed to insure accuracy of collected data.

CONCLUSION

During the first year of funding, we developed the necessary infrastructure to implement this study protocol by developing customized self-report questionnaires, written scripts and outlines for initial and follow-up visits, and electronic databases to monitor recruitment, tracking, and contraceptive discontinuation. Additionally, we initiated recruitment of our cohort. To date, a total of 90 women have completed their initial medical visits and initial self-report measures and 47 subjects have been seen for their 3-month follow-up visit. Although some turn over of study personnel was experienced during Year 1, we will have a complete staff by 3 November. A fourth employee stationed at WHMC will be funded by the department of Obstetrics and Gynecology.

Subject recruitment will be the highest priority for Year 2. Although we were to have enrolled a total of 225 subjects by the end of Year 1, our efforts were hampered by the fact that many potential subjects were currently using hormonal contraception. This obstacle has been addressed by decreasing the amount of time women must be off contraceptives prior to enrollment. In addition, many otherwise eligible civilian women who receive care at UTMB exhibited excessive body weight.

To meet our projected enrollment of 225 subjects at UTMB by March of 1998, we will have to enroll approximately 26 women per month for the next 6 months. At WHMC, we will have to enroll 34 per month for the next 6 months. Hiring of a full-time research assistant at WHMC will allow us to substantially increase recruitment efforts at WHMC. Direct mail solicitation at both sites, use of electronic mail to publicize our study, and expanding our recruitment efforts to other military bases in the San Antonio area should help achieve these goals. Other recruitment strategies will be identified and implemented as needed. In the event

that we are unable to adhere to our original timeline for recruitment (450 subjects in 12 months), we will confer with our scientific officer, Dr. Patricia Mudrow, to discuss alternative strategies. These may include extending the period of enrollment or determining if our specific aims could be achieved with a smaller cohort.

Appendix A

Visit Outlines

Initial Visit Checklist

3 Month Follow-up Checklist

6 Month Follow-up Checklist

Initial Exam and Interview Script

Visit Outlines

I. INITIAL VISIT AND EXAM

- A. INTRODUCTION AND PRERECRUITMENT QUESTIONNAIRE
- B. HAVE PATIENT SIGN CONSENT FORM
- C. CALL BONE SCAN--GREG AT X 22921
- D. OBTAIN URINE SAMPLE FOR PREGNANCY AND CULTURE/ SENSITIVITY
- E. OBTAIN HEIGHT/WEIGHT
- F. FILL OUT MEDICAL HISTORY FORM
- G. PT HAS TO MAKE DECISION ON WHICH CONTRACEPTIVE METHOD THEY CHOOSE.
- H. PT DOES QUESTIONNAIRES
- I. PHYSICAL EXAM
- J. HIRSUTISM CHECK/FAT MEASUREMENT
- K. ESCORTED TO THE LAB FOR CARDIAC AND COULTER PROFILE.
- L. ESCORT PT TO THE RADIOLOGY FOR DEXA.
- M. PICK-UP PT FROM RADIOLOGY.
- N. RECEIVE THE CHOSEN CONTRACEPTION/DIRECTION AND EXPLANATION OF POTENTIAL SIDE-EFFECT.
- O. GIVE PT THE BLEEDING CALENDAR AND DISCUSS FORM W/ THEM.
- P. GIVE AND DISCUSSED FOOD DIARY.
- P. FOR PT RECEIVING DEPO-PROVERA INJECTION---DISCUSSED SIDE EFFECTS,ADMINISTRATION, AND APPT TIMES
- Q. RECEIVE APPOINTMENT TIME /\$25

*WHEN APPROPRIATE TAPE SESSIONS*****

3 MONTH FOLLOW-UP VISIT

- A. GREETINGS
- B. OBTAIN WEIGHT
- C. OBTAIN URINE SPECIMEN FOR CULTURE
- D. CHECK VITAL SIGNS
- E. COLLECT MENSTRUAL CALENDARS/AND PILL PACKS/FOOD DIARY
- F. CONDUCT STRUCTURED INTERVIEW
- G. HAVE PATIENT FILL OUT QUESTIONNAIRE
- H. GIVE PILL OR THE DEPO-PROVERA
- I. GO OVER MENSTRUAL CALENDAR
- J. MAKE APPT AND \$25.

*****WHEN APPROPRIATE TAPE SESSIONS*****

6 MONTH FOLLOW-UP VISIT

- A. GREETINGS
- B. OBTAIN WEIGHT
- C. OBTAIN URINE SPECIMEN FOR CULTURE
- D. CHECK VITAL SIGNS
- E. HIRSUTISM CHECK
- F. COLLECT MENSTRUAL CALENDARS/AND PILL PACKS
IF DEPO-PATIENT--ASK THEM HOW THEY ARE DOING
- G. CONDUCT STRUCTURED INTERVIEW
- H. HAVE PATIENT FILL OUT QUESTIONNAIRE
- I. GIVE PILL OR THE DEPO-PROVERA
- J. GO OVER MENSTRUAL CALENDAR
- K. MAKE APPT AND \$25.

*****WHEN APPROPRIATE TAPE SESSION*****

9 MONTH FOLLOW-UP VISIT

- A. DEPO-PROVERA ONLY
- B. MAKE APPT/GIVE \$25

12 MONTHS VISIT

- A. GREETINGS
- B. OBTAIN URINE SAMPLE FOR CULTURE/ SENSITIVITY
- C. OBTAIN HEIGHT/WEIGHT
- D. UPDATE THE MEDICAL HISTORY FORM
- E. COLLECT THE PILL PACKS AND MENSTRUAL CALENDAR
- F. PT DOES QUESTIONNAIRE/INTERVIEW
- G. PHYSICAL EXAM
- H. HIRSUTISM CHECK
- I. ESCORTED TO THE LAB FOR CARDIAC AND COULTER PROFILE.
- J. RECEIVE THE CHOSEN CONTRACEPTION/DIRECTION AND EXPLANATION
OF POTENTIAL SIDE-EFFECT.
- K. GIVE PT THE BLEEDING CALENDAR AND DISCUSS FORM W/ THEM.
- L. FOR PT RECEIVING DEPO-PROVERA INJECTION---DISCUSSED SIDE
EFFECTS, ADMINISTRATION, AND APPT TIMES
- M. RECEIVE APPOINTMENT TIME /\$25

*WHEN APPROPRIATE TAPE SESSIONS*****

15 MONTHS VISIT

- A. DEPO-PROVERA ONLY
- B. MAKE APPT/GIVE \$25

18 MONTHS VISIT

- A. GREETINGS
- B. OBTAIN WEIGHT

- C. CHECK VITAL SIGNS
- D. HIRSUTISM CHECK
- E. COLLECT MENSTRUAL CALENDARS/AND PILL PACKS
IF DEPO-PATIENT--ASK THEM HOW THEY ARE DOING
- F. CONDUCT STRUCTURED INTERVIEW
- G. HAVE PATIENT FILL OUT QUESTIONNAIRE
- H. GIVE PILL OR THE DEPO-PROVERA
- I. GO OVER MENSTRUAL CALENDAR
- J. MAKE APPT AND \$25.

*WHEN APPROPRIATE TAPE SESSIONS*****

21 MONTHS VISIT

- A. DEPO-PROVERA ONLY
- B. MAKE APPT/GIVE \$25

24 MONTHS VISIT/FINAL VISIT

- A. GREETINGS
- B. CALL BONE SCAN---GREG AT X 22921
- C. OBTAIN HEIGHT/WEIGHT
- D. UPDATE MEDICAL HISTORY FORM
- E. PT DOES QUESTIONNAIRE
- F. PHYSICAL EXAM
- G. HIRSUTISM CHECK
- H. ESCORTED TO THE LAB FOR CARDIAC AND COULTER PROFILE.
- I. ESCORT PT TO THE RADIOLOGY FOR DEXA.
- J. PICK-UP PT FROM RADIOLOGY.
- K. RECEIVE THE CHOSEN CONTRACEPTION/DIRECTION AND
EXPLANATION OF POTENTIAL SIDE-EFFECT.
- L. FOR PT RECEIVING DEPO-PROVERA INJECTION---DISCUSSED SIDE
EFFECTS, ADMINISTRATION, AND APPT TIMES
- M. TELL OCP PT'S NAME OF THEIR OCP/GIVE \$25

*****WHEN APPROPRIATE TAPE SESSION*****

Initial Visit Checklist

Sometime before the appointment day:

- _____ Print out 3 copies of the verification sheet (If you have a UH#)
- _____ Fill out and fax study number sheet to Special Accounts. Call them to make sure they received it. (x74875) Date faxed _____
- _____ Call radiology to set up bone scan appointment (x22921--may need to schedule this for a day different from initial visit day. Note: Greg doesn't like to accept appointments after 2:00pm.)
- _____ Fax dexta Xerox to radiology. Date faxed _____
- _____ Prepare folder.

The Day Before:

- _____ Confirm appointment
- _____ Inform Maria or Chris (our unit clerks) of the appointment. (Give them the PI sheet if patient does not have a UH#)
- _____ Make sure you are stocked with needed materials
- _____ Confirm dexta scan appointment (if time permits)
- _____ Confirm that case # has been assigned. _____ Name of person confirmed with.

The Day of Appointment:

At least an hour before patient arrives:

- _____ Drop verification sheet off to Carmen (she will print out IOC stickers and DPD stickers--for billing)
- _____ Get stickers from Carmen

When Patient arrives:

- _____ Greet.
- _____ Urine
- _____ Pregnancy test
- _____ Take to exam room and explain study (background, etc.)
- _____ Have sign three consent forms, and initial every page of one form.
- _____ Patient and get height and weight--lbs. and inches
- _____ Introduce paper work. (drk blue form, brown, med histories, volunteer registry sheet, 24-hour food, demographics, 2 HIV forms, eligibility questionnaire-if not already done.)
- _____ Show patient where to find you when they are done with paper work.
- _____ Prepare forms (fill-out, place stickers where appropriate, etc.)
- _____ Get bone scan--pt. will need to change into scrubs and driven to McCullough, 2nd floor.
- _____ Bring nuclear medicine form. (She will need to be in scrubs and not wearing anything metal.)
- _____ Nurse's exam:
 - _____ pelvic
 - _____ bloodwork

- _____ (fill out salmon colored form--don't forget to check HIV if applicable.)
- _____ enter information into computer to print out forms
- _____ hirsutism
- _____ body fat measurements
- _____ nurse assessment form (lt blue bubble form)
- _____ go over contraceptive education, include handouts.

When all through with above:

- _____ provide contraception

If getting Depo-Provera:

- _____ give Depo shot if only if she is on her period.
- _____ schedule (tentative) appointment for shot. If pt is **not** on her period at time, she should call us to reschedule.

If getting pill,

- _____ randomly assign pt to red or green pills (use chart)
- _____ provide packs numbered 1-4 (be sure and note serial number)
- _____ inform to bring empty pill packs at follow-up.
- _____ record (tentative date pt should begin pills)
- _____ inform pt. to call us when they begin their period (She should start the pill on the first Sunday after she starts her period.)
- _____ provide with a weeks worth of condoms and foam.
- _____ give new menstrual calendar (inform to bring calendar back to next appointment.)
- _____ go over Patient Responsibilities sheet. (record injection appointment for Depo patients.)
- _____ have pt. sign money form
- _____ give money (unless going on Depo, then she will get paid when she gets her shot)
- _____ Call Jyotsana to let her know we have a urine sample for Dr. Nowicki (ext. 21133).
- _____ include Xerox copies of the exam form, and med. history forms in the specimen bag.

Coding

On Scantron:

- _____ Code labwork on nurses assessment form
 - _____ lab results from IRMA (blood, pap smear, probe)
 - _____ dexta results from Greg (obtain from lab or wait for mail)
- _____ Code measurements (whr, triceps, biceps)
- _____ Weight
- _____ Vital signs
- _____ Hirsutism
- _____ Check for any blanks that should be filled
- _____ Check for any blanks on patient questionnaires

Enter in database:

- _____ Medical variables
 - _____ body fat measurements
 - _____ nutrition variables (calories, and fat, protein, and carb grams)
 - _____ ht, weight
 - _____ shot date or pill date to start
- _____ Demographics (enter all data)
- _____ Appointment record (fill in outcome of appointment and any needed notes)

3 Month Follow-up Checklist

The day before:

- _____ 1. Prepare folder. (Fill out all forms as much as possible.)
- _____ 2. Confirm appointment
- _____ 3. Inform Maria or Chris (our unit clerks) of the appointment. Can use print out.

The day of appointment:

- _____ 5. Greet subject
- _____ 6. Get height and weight--lbs. and inches. (At this time, point out nearby restroom.)
- _____ 7. Take to exam room and introduce paper work. (drk. blue form, green form, 24-hour food recall)
 - _____ a. show patient where to find you when they are done with paper work.
 - _____ b. collect empty pill packs (if applicable)
- _____ 8. Nurse's exam:
 - _____ a. nurse assessment form (1t blue bubble form)
 - _____ b. go over menstrual calendar
 - _____ c. vital signs
 - _____ d. if on Depo-Provera, give shot
 - _____ e. urine specimen (call Dr. to let know it's here.)
 - _____ f. 24-hour food-recall
- _____ 9. Make next appointment (whether on pill or Depo, it's 3 months from now)
- _____ 10. When all through with above, provide:
 - _____ contraception (pills--inform pt. to bring in empty pill packs at next appt.)
 - _____ new menstrual calendar (instruct patient to bring in to next appt.)
 - _____ money
 - _____ have pt. sign form

Coding

On Scantron:

- _____ Code vital signs
- _____ If didn't get at Initial Visit, code measurements (whr, triceps, biceps)
- _____ Code weight
- _____ Menstrual calendar information
- _____ If on pills, pill pack information
- _____ Check for any blanks that should be filled
- _____ Check for any blanks on patient questionnaires

Enter in the computer:

- _____ Medical variables
 - _____ nutrition variables (calories, and fat, protein, and carb grams)
 - _____ weight
 - _____ if on Depo, shot date
- _____ Demographics--any new data (be sure to print out a new form for the pt.'s file)
- _____ Appointment record
 - _____ Fill in outcome of appointment and any needed notes
 - _____ Enter appt for next follow-up

6 Month Follow-up Checklist

The day before:

- _____ 1. Prepare folder. (Fill out all forms as much as possible.)
- _____ 2. Confirm appointment
- _____ 3. Inform Maria or Chris (our unit clerks) of the appointment.

The day of appointment:

- _____ 5. Greet Patient
- _____ 6. Get height and weight--lbs. and inches. (At this time, point out nearby restroom.)
- _____ 7. Take to exam room and introduce paper work. (drk blue form, green form, 24-hour food recall)
 - _____ a. show patient where to find you when they are done with paper work.
 - _____ b. collect empty pill packs (if applicable)
- _____ 8. Nurse's exam:
 - _____ a. nurse assessment form (lt blue bubble form)
 - _____ b. go over menstrual calendar
 - _____ c. vital signs
 - _____ d. if on depo-provera, give shot
 - _____ e. urine specimen (call Dr. to let know it's here.)
 - _____ f. hirsutism check
- _____ 9. Make next appointment (if on pill, 6 months later, on depo, 3 months later)
- _____ 10. When all through with above, provide:
 - _____ a. money
 - _____ b. have pt. sign form
 - _____ c. contraception (pills--inform pt. to bring in empty pill packs at next appt.)
 - _____ d. new menstrual calendar (instruct patient to bring in to next appt.)

Coding

On Scantron:

- _____ Code vital signs
- _____ If didn't get at Initial Visit, code measurments (whr, triceps, biceps)
- _____ Code weight
- _____ Menstrual calendar information
- _____ If on pills, pill pack information
- _____ Check for any blanks that should be filled
- _____ Check for any blanks on patient questionnaires

Enter in the computer:

- _____ Medical variables
 - _____ nutrition variables (calories, and fat, protein, and carb grams)
 - _____ weight
 - _____ if on depo, shot date
- _____ Demographics--any new data (be sure to print out a new form for the pt.'s file)
- _____ Appointment record
- _____ Fill in outcome of appointment and any needed notes
- _____ Enter appt for next follow-up

Initial Exam and Interview Script

1. Collect urine specimen for UTI study. (Only for UTMB site)

Now I need you to come with me to the lab, so that you can leave a clean-catch urine specimen. We will use it to test for both infection and pregnancy. First you will need to wash your hands with soap and water then dry them thoroughly. You will then open the package containing the specimen cup and towelettes. Go ahead and open the specimen container, being careful to lay the lid top side up, so that you don't contaminate the inside of it. Do not let anything touch the inside of the container or its lid, including your hands. Then, take one of the moist towelettes and wipe each labia front to back and discard it into the toilet. Take the second towelette and wipe down the middle, between the labia. Be sure to wipe front to back. You will then urinate a small amount into the toilet, stop, place the container between your legs, under your stream of urine, and urinate into the container. Be sure not to touch any part of the cup to your legs or body, to prevent contamination. When you finish, screw the lid on the container and leave it in the window to the lab. *(use this specimen to get a few drops of urine for UPT)*

2. Complete the initial exam.

A. Review medical history sheet.

Determine if there are any exclusion criteria met, if not, proceed with study group assignment.

B. Assignment to method study group.

Now it is time for you to decide which method of contraception you would like to use.

1. Do you have any additional questions about either of the methods of birth control that we will be comparing?
2. *For pill users:* As you know, we are comparing two types of pills (Ortho Novum 1/35 & Orthocept) and you will be randomly assigned to one of these pills. Each pill is equally effective at preventing pregnancy. Neither I, nor the provider will know which pill you are using during the study. This is to ensure that we conduct accurate comparisons without bias. After your exam, I will be giving you your pills, explaining how to use them and when to start. At the end of the study, you will be told what pill type you were taking.
3. *For Depo users:* After your exam, we will schedule you a return appointment, or if possible, you will get your shot today.

C. Explanation of exam/lab procedures.

This is the exam room that we will be using. Please have a seat while I take your blood pressure. _____ is a female nurse practitioner, and will be your care provider throughout the study. After I record your information, and you are ready, she will be in to meet with you and do your exam. *(record blood pressure)*. Have you ever had a pelvic examination before? *If patient answers 'no', explain exam procedures.* All the results from your lab work will take a few days to get back to us. We will send you a letter if all your results are normal. If there is a problem, we will notify you of your results, and arrange for any necessary follow-up. It is very important that you give us good contact information, so that we are able to notify you of your results.

Here is a gown for you to wear during your exam. Please remove your clothes, including your bra and underwear, then put on the gown. I'll be back in a few minutes to see if you are ready.

3. Complete self-report measure

These are questions about your general health, health habits, sexual history, mood and menstruation symptoms. In addition, we would like to better understand your opinion and attitudes about condoms. Please take your time and answer them completely. There are no right or wrong answers, we just want to know exactly how you feel. Please let me know if you need help with understanding any of the questions.

4. Have Cardiac Risk Panel and Coulter Profile drawn in lab.

Now we'll go to the lab where you will have your blood drawn. This will be to measure your cholesterol, hemoglobin and hematocrit levels.

5. Be escorted to Nuclear Medicine for scan.

We will now go to Radiology to have your x-ray taken. This is to measure the density of your bones. It will take about 45 minutes and is similar to receiving a chest x-ray. The exposure to radiation is minimal and should in no way be harmful. You will have another x-ray taken at the end of the study in 24-months.

6. Give patient bleeding calendar and directions for completing scannable calendar.

Starting the day you take your first pill or receive your first shot, you will keep a record of your menstrual cycle, using this calendar. Each day you will record whether you have no bleeding at all, just spotting, or bleeding. Days of bleeding are days in which you need to use 1 or more sanitary pads for protection. Days of spotting are those days in which the bleeding is so light, you use a panty liner only or don't need any sanitary protection. Let's pretend you were starting your contraception today. As you can see, the months are listed along the left side of this calendar, and the days of the month are shown by the numbers going across the top. Today is the ___ day of the month, and you are not bleeding. We'll find today's date by going down the calendar until we get to this month, and going across to the correct day. 'X's are for days of bleeding, 'S's are for days of spotting, and 'O's are for days of no bleeding. You would fill-in the 'O' bubble under today's date to show that you are not bleeding. You will do the same thing every day, recording days with no bleeding, days of just spotting, and days of bleeding for the next three months. These directions are on the calendar, or you can call us if you ever have any questions. It is very important that you bring this calendar with you to every follow-up appointment so we can see how you are doing.

7. Receive their chosen form of contraception, directions on use and explanation of potential side effects.

A. For patients on pill regimen:

Here is your first supply of pills. We have repackaged them so that the pill name is not on the container. Otherwise, they are the exact same pills you would receive at a pharmacy. These will last for the next 4 months only. We will see you back at the clinic in about 3 months for your first follow-up. We are giving you the extra pack just in case a problem arises with keeping your appointment. You will need to bring back all of these packs, regardless if they are empty of pills or have some remaining, when you return in 3 months. Try to not be late for your appointment. Do not stop taking the pills before your next visit, as this could put you at risk for pregnancy.

You will begin taking your pills on the first Sunday of your next menses. Should your period start in the middle of the week, you will begin taking your pills the following Sunday. If your period starts on the weekend, take your first pill that Sunday. We suggest you include your pill-taking with other daily activities, so that it is easier to remember. For example, many women take their pills at bedtime, keeping them with their toothbrush so that it becomes part of their bedtime routine. Take the entire pack of pills. When you are taking the colored pills, you will have your menses. Keep taking the pills until they run out. The day after your pills run out, start your next pack of pills. You will need to use an additional form of contraception, such as condoms and foam for the first full month of pills to prevent pregnancy. After that, the pills should prevent pregnancy and condoms should be used for safe sex.

Should you forget to take a pill one day, take that pill as soon as you remember the next day, then take your next pill at the usual time. If you don't remember until it is time to take the next pill, take two at that time. If you forget your pills two days in a row, take two pills each of the next two days following the same directions. You should use additional protection from pregnancy, such as condoms if this happens. If something should happen and you forget your pills 3 or more days in a row, you must stop your pills for the rest of that cycle, and you will begin a new pack starting the first Sunday of your next menses. Please contact us if this happens, so that we can help you get back on schedule.

Remember, it is very important that you bring back all four of these packs, including any pills that you haven't taken, when you return in 3 months. I'm also giving you written directions for taking your pills to help you get started. If you ever have any questions, please call us. Included in your bag are the package inserts for both pill types. Because you may be taking either type of pill, we have included information on both. Also, here is a brochure that explains possible risks and side effects associated with taking birth control pills. Be sure that you bring back all 4 pill packs, including any of the pills that you haven't taken, to your next appointment in 3 months. Do you have any questions about your contraception or about this project? Should you ever have any questions about your contraception or this project, please call us at (this number).

B. For patients receiving Depo-Provera® injection:

Because Depo-Provera® needs to be given during the first 7 days of your menstrual cycle, you will need to call us the first day of your next period so that I can make an appointment for you. Be sure and call as soon as possible so that we can get you in within 7 days. Here is the number that you will call. According to the date of your last menses, you are due to start your next period around _____. As a reminder, we will be checking with you about twice a week by phone, until your period starts, so that we can schedule your first shot.

On day of injection: You will need to use an additional form of contraception, such as condoms and foam, to prevent pregnancy for the next 2-4 weeks. After that time, the Depo-Provera® should prevent pregnancy and you should continue to use condoms for safe sex. You will need to get your next shot 12 weeks from today. We'll schedule this appointment for you today and give you the appointment sheet. You will get your next shot whether or not you are on your period. Remember, it is very important that you come back for your follow-up. I am giving you a package insert that has information on Depo-Provera®. Also, here is a brochure that that explains possible risks and side effects

associated with Depo-Provera®. Do you have any questions about your contraception or about this project? Should you ever have any questions about your contraception or this project, please call us.

8. Receive next scheduled appointment and phone numbers (both for clinic and after-hours).

Today, we will schedule your 3-month follow-up visit and give you an appointment card. It is very important that you keep your appointment so that you don't run out of pills/aren't late for your next injection. We will also send you a reminder one month before your appointment. Should there be any problems with keeping this appointment, please call us immediately to reschedule. Here are the phone numbers to call with questions or problems. This is (the number) to use Monday through Friday, between 8 AM and 5 PM. If you need to contact us after hours, please use (this number.)

9. When appropriate, tape session

For training purposes, I would like to record this session. I will not record your name, just our conversation regarding the project.

3, 6, 18-Month Follow-Up

1. Complete the 3, 6, or 18-Month questionnaire.

Thank you for coming in today. I'm going to ask you to fill-out a questionnaire similar to the one you completed at the beginning of the study. It's important that you tell us exactly how you feel, there are no right or wrong answers.

2. Complete self-report measure.

3. Record weight of subject.

4. For patients on pill regimen:

A. Count and document the number of remaining pills in patient's (4 or 7) packs.

1. *If patient is having trouble with missing pills, provide counseling/suggestions on remembering to take them and the importance of consistency in pregnancy prevention.*
2. *It is important to be helpful and nonjudgemental so that accurate data is collected.*

B. Conduct structured interview on side-effects and satisfaction.

C. Supply patient with next 4 packs of pills at 3 months and 7 packs at 6 and 18 months.

5. For patients on Depo:

A. Ask patient if they have any questions or are having any problems with their Depo.

B. Conduct structured interview on side-effects and satisfaction.

C. Give patient injection.

4. Collect specimen for UTI study. (For 3 and 6 month follow-up)

Now I need you to come with me to the lab, so that you can leave a urine specimen. You will be leaving a clean-catch specimen like you did when you started the project. Remember, first you will need to wash your hands with soap and water then dry them thoroughly. You will then open the package containing the specimen cup and towelettes. Go ahead and open the specimen container, being careful to lay the lid top side up, so that you don't contaminate the inside of it. Do not let anything touch the inside of the container or its lid, including your hands. Then, take one of the moist towelettes and wipe each labia front to back and discard it into the toilet. Take the second towelette and wipe down the middle, between the labia. Be sure to wipe front to back. You will then urinate a small amount into the toilet, stop, place the container between your legs, under your stream of urine, and urinate into the container. Be sure not to touch any part of the cup to you legs or body, to prevent contamination. When you finish, screw the lid on the container and leave it in the window to the lab.

5. Collect and complete patient's bleeding calendar.

A. Now, I'll need to get your bleeding calendar from you.

Check for completeness: does each month have days with and without bleeding? If not, ask:

B. Have your periods been regular, and have you had one each month, I noticed there are no days marked for bleeding/non-bleeding during month. Complete as needed, be sure that any irregularities are consistent with answers to self-report questionnaire. *If they are not, patient may need help in understanding*

either the questionnaire or the calendar. Encourage patient to complete the calendar as much as possible. Be sure not to 'lead' patients into answering questions for which they are unsure of the answer, or don't remember.

- C. Here is your next calendar. You will continue to record your bleeding patterns for the next (3 or 6) months. You will need to bring this back at your next follow-up.

6. Receive next scheduled appointment and phone numbers (both for clinic and after-hours).

Today, we will schedule your next follow up in (3 or 6)-months and give you an appointment card. Remember, it is very important that you keep your appointment so that you don't run out of pills/aren't late for your next injection. We will also send you a reminder one month before your appointment. Should there be any problems with keeping this appointment, please call us immediately to reschedule. Here are the phone numbers to call with questions or problems. This is (the number) to use Monday through Friday, between 8 AM and 5 PM. If you need to contact us after hours, please use (this number.)

7. When appropriate, tape session.

We are trying to make sure that all of our patients are receiving the same information when they come to see us because it is important to the project that we are consistent. In order to be sure of this, I need to tape this session. I will not record your name, just our conversation regarding your progress.

24 Month Follow-up Script

I. GREETING AND GET WEIGHT

HI! HOW ARE YOU DOING TODAY. THANK YOU FOR COMING IN.
LET'S GET YOUR WEIGHT AND THEN WE'LL GO TO MY OFFICE AND TALK.

II. CALL GREG-X 2-2921 FOR DEXA

III. COLLECT AND COMPLETE PATIENT'S BLEEDING CALENDAR PILL PACKS AND FOOD DIARY AND LET THEM FILL OUT QUESTIONNAIRE.

NOW, I'LL NEED TO GET YOUR BLEEDING CALENDAR, THE FOOD DIARY AND YOUR PILL PACKS FROM YOU. WHILE I'LL GO OVER THEM, I WOULD LIKE YOU TO FILL OUT THESE QUESTIONNAIRES. THIS QUESTIONNAIRES ARE SIMILAR TO THE ONES YOU FILL OUT AT THE BEGINNING OF THE STUDY AND LIKE BEFORE THERE ARE NO RIGHT OR WRONG ANSWERS. PLEASE ANSWER THEM AS HONESTLY AS YOU POSSIBLY CAN.

CHECK FOR COMPLETENESS: DOES EACH MONTH HAVE DAYS WITH AND WITHOUT BLEEDING? IF NOT, ASK:

HAVE YOUR PERIODS BEEN REGULAR, AND HAVE YOU HAD ONE EACH MONTH, I NOTICED THERE ARE NO DAYS MARKED FOR BLEEDING/NON-BLEEDING DURING MONTH.

COMPLETE AS NEEDED, BE SURE THAT ANY IRREGULARITIES ARE CONSISTENT WITH ANSWERS TO SELF-REPORT QUESTIONNAIRE OR STRUCTURED INTERVIEW. IF THEY ARE NOT, PATIENT MAY NEED HELP IN UNDERSTANDING EITHER THE QUESTIONNAIRE OR THE CALENDAR. ENCOURAGE PATIENT TO COMPLETE THE CALENDAR AS MUCH AS POSSIBLE. BE SURE NOT TO 'LEAD' PATIENTS INTO ANSWERING QUESTIONS FOR WHICH THEY ARE UNSURE OF THE ANSWER, OR DON'T REMEMBER.

FOR PATIENTS ON PILL REGIMEN:

COUNT AND DOCUMENT THE NUMBER OF REMAINING PILLS IN PATIENT'S 7 PACKS. *IF PATIENT IS HAVING TROUBLE WITH MISSING PILLS, PROVIDE COUNSELING/SUGGESTIONS ON REMEMBERING TO TAKE THEM AND THE IMPORTANCE OF CONSISTENCY IN PREGNANCY PREVENTION. IT IS IMPORTANT TO BE HELPFUL AND NOT JUDGMENTAL SO THAT ACCURATE DATA IS COLLECTED.*

IV. CONDUCT STRUCTURED INTERVIEW.

V. UPDATE THE MEDICAL HISTORY.

FIRST, WE NEED TO UPDATE YOUR MEDICAL HISTORY SHEET. *(FOLLOW INSTRUCTIONS ON MED HX SCRIPT)*

VI. COMPLETE THE ANNUAL EXAM.

EXPLAIN THE EXAM TO THE PATIENT.

AFTER I RECORD YOUR INFORMATION, AND YOU ARE READY, PROVIDER'S NAME WILL BE IN TO DO YOUR EXAM.

REMEMBER, ALL THE RESULTS FROM YOUR LAB WORK WILL TAKE A FEW DAYS TO GET BACK TO US. WE WILL ONLY NOTIFY YOU OF THESE RESULTS IF THERE IS A PROBLEM. IF ALL YOUR RESULTS ARE NORMAL, WE WILL NOT NEED TO CONTACT YOU BEFORE YOUR NEXT SCHEDULED FOLLOW-UP. IT IS VERY IMPORTANT THAT YOU GIVE US GOOD CONTACT INFORMATION, SHOULD WE NEED TO NOTIFY YOU OF YOUR RESULTS.

VI. HAVE CARDIAC RISK PANEL AND COULTER PROFILE DRAWN IN THE LAB.

NOW WE'LL GO TO THE LAB AND YOU'LL GET YOUR BLOOD DRAW TO CHECK YOUR CHOLESTEROL AND SCREEN FOR ANEMIA.

VII. BE ESCORTED TO NUCLEAR MEDICINE FOR DEXA.

WE WILL NOW GO TO RADIOLOGY TO HAVE YOUR X-RAY TAKE. THIS IS TO MEASURE THE BONE DENSITY. THIS IS THE SAME X RAY YOU DID AT THE BEGINNING. IT WILL TAKE ABOUT 45 MINUTES AND IS SIMILAR TO RECEIVED A CHEST X-RAY. THE EXPOSURE TO RADIATION IS MINIMAL AND SHOULD IN NO WAY BE HARMFUL.

VIII. GIVE THE DEPO/OCP

FOR PATIENTS ON PILL REGIMEN:

SUPPLY PATIENT WITH 3 MONTHS SUPPLY AND WRITE A PRESCRIPTION FOR A YEAR SUPPLY OF THE SAME OCP OR AN OCP SIMILAR TO WHAT THEY ARE ON WHICH IS ON THE FORMULARY.

FOR PATIENTS ON DEPO:

GIVE PATIENT INJECTION.

IX. CLOSING STATEMENT.

X. WHEN APPROPRIATE, TAPE SESSION.

WE ARE TRYING TO MAKE SURE THAT ALL OF OUR PATIENTS ARE RECEIVING THE SAME INFORMATION WHEN THEY COME TO SEE US BECAUSE IT IS IMPORTANT TO THE PROJECT THAT WE ARE CONSISTENT. IN ORDER TO BE SURE OF THIS, I NEED TO TAPE THIS SESSION. I WILL NOT RECORD YOUR NAME, JUST OUR CONVERSATION REGARDING YOUR PROGRESS.

Appendix B

Initial

Follow-up

All Visit

Nursing Assessment

Discontinuation Assessment

INITIAL Contraception Study

This questionnaire asks about your past medical history, past and current health behaviors, knowledge of and past use of contraception. You will complete this questionnaire **ONLY** at your first visit. Although some of the questions are sensitive, please remember that this information is confidential and will **NOT** appear in your medical chart. Read each question carefully. If you do not understand a particular question, please ask the research nurse for help. Remember, do **not** put your name on this questionnaire.

TODAY'S DATE												
	0	1										
	0	1	2	3	4	5	6	7	8	9		
	0	1	2	3								
	0	1	2	3	4	5	6	7	8	9		
	0	1	2	3	4	5	6	7	8	9		
	0	1	2	3	4	5	6	7	8	9		

SUBJECT NO												
	U	W										
	0	1	2	3	4	5	6	7	8	9		
	0	1	2	3	4	5	6	7	8	9		
	0	1	2	3	4	5	6	7	8	9		

VISIT

- ☐ 3 month ☐ 18 month
☐ 6 month ☐ 24 month
☐ 12 month

METHOD OF COMPLETION

- ☐ person ☐ phone

SECTION 1:

1. What was the last grade in school you completed?

- ☐ less than 7 ☐ 8 ☐ 10 ☐ 12 ☐ Some college
☐ 7 ☐ 9 ☐ 11 ☐ Received my G.E.D. ☐ Received college degree

2. Are you married? ☐ Yes ☐ No

- Do you have a current boyfriend or partner? ☐ No ☐ Yes

How many months have you been going out?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

months

How old is your current boyfriend or partner?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

years

How would you describe this relationship? ☐ serious ☐ going out/dating ☐ casual/friends

3. At what age did you start your period?

- ☐ 8 ☐ 10 ☐ 12 ☐ 14 ☐ 16 ☐ 18
☐ 9 ☐ 11 ☐ 13 ☐ 15 ☐ 17 ☐ 19

4. Have you ever taken birth control pills?

- ☐ No ☐ Yes

At what age did you start taking birth control pills?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

About how long have you been taking birth control pills?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

What was the name of the last pill you took?

How long did you use that pill?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

months

How satisfied were you with these pills?

- ☐ very satisfied ☐ satisfied ☐ somewhat satisfied ☐ not very satisfied ☐ not at all satisfied

5. If you were NOT satisfied with these pills, was it because: (Mark all that apply)

- ☐ couldn't remember to take ☐ side-effects like acne ☐ made me gain weight ☐ other reason (Please write in.)
☐ breakthrough bleeding and spotting ☐ health problems ☐ partner did not want me to take
☐ desired to get pregnant ☐ too expensive ☐ never took pills

6. Have you ever had any medical problems while you were pregnant or when you delivered?

- ☐ never pregnant ☐ no ☐ yes

Was it...

- ☐ an infection (Please write in.)
☐ high fever
☐ gained more than 40 lbs.
☐ hospitalized due to high blood pressure during pregnancy
☐ hospitalized for premature labor
☐ delivered baby prematurely (before 37 weeks)
☐ delivered a baby who weighed less than 5.5 lbs.
☐ other (Please write in.)

7. How old were you when you had your first child?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

years

- ☐ haven't had a child

8. IN YOUR LIFETIME, how many times have you had a sexually transmitted disease (VD) such as gonorrhea, trich, chlamydia, syphilis, herpes, or warts?
☐ none ☐ 1 ☐ 2 ☐ 3 ☐ 4 or more
9. IN YOUR LIFETIME, have you ever had a urinary tract infection?
☐ No ☐ Yes → How many have you had? ☐ none ☐ 1 ☐ 2 ☐ 3 ☐ 4 or more
10. IN YOUR LIFETIME, have you ever seen a doctor because of pain associated with menstruation? ☐ No ☐ Yes
11. IN YOUR LIFETIME, how often have you missed work because of painful menstruation?
☐ I don't work ☐ never ☐ occasionally ☐ every other period ☐ every period
12. Have you ever smoked cigarettes?
☐ never
☐ once or twice
☐ occasionally, but not regularly
☐ regularly in the past
☐ regularly now
- How many years has it been since you smoked regularly?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

☐ less than half of pack
☐ about 1/2 pack
- How many years did you smoke?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

☐ about 1 pack per day
☐ 1 1/2 or more packs per day
- How many years have you been smoking?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
13. At what age did you FIRST have sexual intercourse?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

 years ☐ Have not had sex
14. Since you started having sexual intercourse, how many different sexual partners have you had?
☐ none ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 or more
15. During the LAST 12 MONTHS, how many different sexual partners have you had?
☐ none ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 or more
16. During the LAST THREE MONTHS, what method of birth control were you using? (Mark all that apply)
☐ None ☐ Sponge ☐ Withdrawal ☐ Abstinence ☐ Rhythm
☐ Birth control pills ☐ Condoms ☐ IUD ☐ Depo-Provera ☐ Other

SECTION 2:

We would like to understand the reason you chose the birth control pill or shot method.

1. Why did you select either the pill or shot method? (Mark all that apply)
☐ not satisfied with past pills ☐ menstrual bleeding irregularities ☐ fearful of shots ☐ convenience
☐ confidence in effectiveness ☐ curiosity ☐ had heard negative things ☐ side-effects
☐ wanted to try different method ☐ health reasons ☐ about the other method ☐ weight gain
2. How concerned would you be if your hormonal method of birth control caused you to gain weight?
☐ very concerned ☐ concerned ☐ somewhat concerned ☐ rarely concerned ☐ not concerned at all
3. How concerned would you be if your hormonal method of birth control caused mood swings?
☐ very concerned ☐ concerned ☐ somewhat concerned ☐ rarely concerned ☐ not concerned at all
4. How concerned would you be if your hormonal method of birth control caused you to bleed/spot in between your normal periods?
☐ very concerned ☐ concerned ☐ somewhat concerned ☐ rarely concerned ☐ not concerned at all
5. How concerned would you be if your method of contraception made you stop having periods?
☐ very concerned ☐ concerned ☐ somewhat concerned ☐ rarely concerned ☐ not concerned at all
6. If you had been taking a prescription method of birth control and stopped having periods, how likely would you think that you were pregnant?
☐ very likely ☐ likely ☐ somewhat likely ☐ not very likely ☐ not likely at all
7. How likely is it that you would feel LESS FEMININE if you stopped having periods?
☐ very likely ☐ likely ☐ somewhat likely ☐ not very likely ☐ not likely at all
8. How advantageous would it be for you to NOT have a period every month?
☐ very advantageous ☐ advantageous ☐ somewhat advantageous ☐ not very advantageous ☐ not advantageous at all

These questions ask about your knowledge of taking birth control pills and the shot method of contraception (Depo-Provera).

9. It's OK to have pills left over at the end of the month. ☐ true ☐ false
10. If a woman misses taking a pill one day, she should take 2 the next day. ☐ true ☐ false
1. As long as a woman takes a pill every day, it does not matter if she takes it at the same time each day. ☐ true ☐ false
2. A woman must get Depo-Provera shots every 3 months. ☐ true ☐ false
3. If a woman gets her Depo-Provera shots regularly and doesn't have menstrual bleeding one month, she could be pregnant. ☐ true ☐ false
4. If a woman gets her next shot 4 months after her last one, it is possible she could become pregnant if that was the only method of birth control. ☐ true ☐ false

FOLLOW UP Contraception Study

This questionnaire asks about your contraceptive use and satisfaction since your last visit. You will complete this same questionnaire at each follow-up visit. Please remember that this information is confidential and will NOT appear in your medical chart. Read each question carefully. If you do not understand a particular question please ask the research nurse for help. Remember, do not put your name on this questionnaire.

TODAY'S DATE											
M	0	1									
M	0	1	2	3	4	5	6	7	8	9	
D	0	1	2	3							
D	0	1	2	3	4	5	6	7	8	9	
Y	0	1	2	3	4	5	6	7	8	9	
Y	0	1	2	3	4	5	6	7	8	9	

SUBJECT NO										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

VISIT

- ☐ 3 month ☐ 18 month
☐ 6 month ☐ 24 month
☐ 12 month

METHOD OF COMPLETION

- ☐ person ☐ phone

SECTION 1:

These questions ask about things that may have happened since your last visit.

1. If you are single, do you have a different boyfriend or current partner SINCE YOUR LAST VISIT _____ months ago?

- ☐ No
☐ Yes

How many months have you been going out?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

months

How old is your current partner or boyfriend?

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

years

How would you describe this relationship? ☐ serious ☐ going out/dating ☐ casual/friends

2. IN THE LAST _____ MONTHS, have you talked by phone with the nurse about any problems or side-effects that you may have experienced?

- ☐ No ☐ Yes



If yes, how helpful
was the nurse?

- ☐ very helpful
☐ helpful

- ☐ somewhat helpful
☐ not very much help

- ☐ not helpful at all

3. Is this the longest period of time you have consistently used a prescription method of contraception? ☐ No ☐ Yes

These next questions ask about your attitudes and feelings toward your method of contraception that you may have had during the last _____ months since your last clinic visit. It is important to answer these questions honestly even though you may not have told the nurse how you felt.

1. IN THE LAST _____ months since your last clinic visit how often...

All of the Time Most of the Time Some of the Time Rarely None of the Time

- | | | | | | |
|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| a. have you had negative feelings about your birth control method?..... | ☐ | ☐ | ☐ | ☐ | ☐ |
| b. did you talk to anyone besides the nurse (friends, family, etc.) about those negative feelings?..... | ☐ | ☐ | ☐ | ☐ | ☐ |
| c. did you need to be encouraged to continue to use your selected birth control method?.. | ☐ | ☐ | ☐ | ☐ | ☐ |
| d. did you ask anyone for encouragement or support in continuing to use your birth control method?..... | ☐ | ☐ | ☐ | ☐ | ☐ |

2. Which people did you ask to encourage or support you? (Mark all that apply)

- ☐ doctor or nurse ☐ boyfriend ☐ mother ☐ sister ☐ did not ask for support or encouragement
☐ husband/partner ☐ girlfriend ☐ father ☐ other _____ (describe relationship)

3. IN THE LAST _____ MONTHS, how satisfied have you been with your contraceptive?

- ☐ extremely dissatisfied ☐ not satisfied ☐ somewhat satisfied ☐ satisfied ☐ extremely satisfied

4. Do you think your current contraceptive method is:

- ☐ easier than other methods you have tried (like condoms, sponges, pills, or implants) ☐ the same difficulty as other methods
☐ more difficult than other methods you have tried

5. BASED ON YOUR EXPERIENCES IN THE LAST _____ MONTHS, how easy has it been for you to use your method of contraception?

- ☐ very easy ☐ easy ☐ somewhat easy ☐ not very easy ☐ not at all easy

6. How effective do you feel your contraceptive is in preventing you from becoming pregnant?

- ☐ very effective ☐ effective ☐ somewhat effective ☐ not very effective ☐ not at all effective

7. How effective do you feel your contraceptive is in preventing you from acquiring a sexually transmitted disease?

- ☐ very effective ☐ effective ☐ somewhat effective ☐ not very effective ☐ not at all effective

8. IN THE LAST _____ MONTHS, have you thought about switching contraceptive methods?
☐ No ☐ Yes → **what have you thought about switching to?** ☐ another type of pill ☐ Norplant ☐ diaphragm ☐ no method
☐ the shot (Depo-Provera) ☐ IUD ☐ sponge or condom only
9. Are the side-effects you have experienced in the LAST _____ MONTHS...
☐ more than I was lead to believe ☐ not as bad as I thought they would be
☐ what I expected to have happen based on what was told me ☐ I have not experienced any side-effects
10. BASED ON YOUR EXPERIENCES IN THE LAST _____ MONTHS, would you recommend your current method of contraception to friends?
☐ strongly recommend using ☐ recommend with some concerns ☐ strongly discourage from using
☐ recommend using ☐ discourage from using
11. BASED ON YOUR EXPERIENCES IN THE LAST _____ MONTHS, what ONE THING do you like MOST about your method:
☐ convenience ☐ reliability ☐ few side-effects ☐ decrease in bleeding
12. BASED ON YOUR EXPERIENCES IN THE LAST _____ MONTHS, what ONE THING do you like the LEAST about your method:
☐ inconvenience ☐ too many side effects ☐ too hard to use ☐ increase in bleeding ☐ change in appetite or weight

These next questions are for those women who are using the PILL method of contraception. If you are using the SHOT method, please STOP and give this form to the research nurse.

1. IN THE LAST _____ MONTHS, have you gotten any pill packs from anywhere else?
☐ No ☐ Yes → **Where did you get them from:** ☐ another doctor or nurse at this clinic ☐ friend or relative
☐ another clinic/health department ☐ other _____
☐ private doctor
→ **Please tell us the name of these pills** _____
→ **Did you take any of those pills?** ☐ No ☐ Yes → **how many?**
- | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
2. Keep thinking of the LAST _____ MONTHS. During those months in which you were taking the birth control pill, how many times did you have pills left over at the end of the month?
☐ none ☐ one month ☐ two months ☐ three months ☐ four months ☐ five months ☐ six months
3. Many people find it hard to take a pill every single day. IN THE LAST _____ MONTHS, how frequently did you miss taking a pill on a day when you should have taken one?
☐ all of the time ☐ about half and half ☐ rarely missed taking a pill
☐ most of the time ☐ some of the time ☐ never missed taking a pill
4. During this same period of time, when you did miss taking a pill at your usual time, how frequently did you take the missed pill later on that same day?
☐ all of the time ☐ about half and half ☐ rarely had to take a pill later
☐ most of the time ☐ some of the time ☐ never missed taking a pill
5. During this same period of time, when you did miss taking a pill, how frequently did you take two together on the next day?
☐ all of the time ☐ about half and half ☐ rarely had to take two together
☐ most of the time ☐ some of the time ☐ never missed taking a pill
6. Again, when you missed a pill since your last visit, did you stop taking the pills altogether?
☐ No ☐ Yes → **Why did you stop taking the pills?** ☐ thought it was best ☐ did not know what else to do
☐ doctor or nurse told me to stop ☐ other reason _____ (describe)
→ **When did you start again?** ☐ started again after period ☐ did not start taking pills again
☐ started again after a number of days ☐ other reason _____ (describe)
7. If you missed two or more pills in a row or stopped taking your pills altogether, how often did you or your partner use condoms or another method of birth control when you had sexual intercourse (diaphragm, foam, or jelly/cream)?
☐ always ☐ very often ☐ often ☐ sometimes ☐ rarely ☐ never
8. SINCE YOUR LAST visit, how often have you taken your pill more than 2 hours before or 2 hours after your usual time?
☐ always ☐ very often ☐ often ☐ sometimes ☐ rarely ☐ never
9. Still thinking about the time SINCE YOUR LAST visit to the clinic, how often have you used somebody else's birth control pill?
☐ always ☐ very often ☐ often ☐ sometimes ☐ rarely ☐ never
10. Now think about the LAST 30 DAYS only. How many days have you forgotten to take a pill in the LAST 30 DAYS?
☐ none ☐ once ☐ twice ☐ 3 or more times
11. Thinking of the days that you forgot to take a pill during the LAST 30 Days, how many different times did you forget to take a pill two or more days in a row?

ALL VISIT

INSTRUCTIONS

-
- A solid black circular stamp, likely a seal or a placeholder, located at the bottom center of the page.

☒ ☐ ☐

- | TODAY'S DATE | | | | | | | | | | |
|--------------|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | | | | | | | | |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | 0 | 1 | 2 | 3 | | | | | | |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

SUBJECT NO											
	(U) (W)										
	(0)	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	
	(0)	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	
	(0)	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	

☐ initial
☐ 3 month
☐ 6 month
☐ 12 month
☐ 18 month
☐ 24 month

☐ person

☐ phone

SECTION 1:

Please tell us about you.

1. Are you: ☐ Single, never married ☐ Divorced ☐ Engaged ☐ Widowed
☐ Separated ☐ Living with partner ☐ Married
2. Who do you currently live with? (Mark all the people who live with you)
☐ By myself ☐ Roommate(s)
☐ Husband ☐ Sister(s) or brothers
☐ Parent(s) ☐ Grandparent(s)
☐ Boyfriend ☐ Friends
☐ My child/children ☐ Other relatives (aunt, uncle, cousin)
3. INCLUDING YOU, how many people live in your household? →

0	1	2	3	4	5	6	7	8	9
0	1	2	3	4	5	6	7	8	9
4. What was the total combined family income during the PAST 12 months. This would include money you and/or your partner made, alimony, child support, and housing allowance.
☐ Less than \$5,000 ☐ \$20,000–29,999
☐ \$5,000–9,999 ☐ \$30,000–49,999
☐ \$10,000–14,999 ☐ \$50,000–74,999
☐ \$15,000–19,999 ☐ \$75,000 and over
5. Are you enrolled in school?
☐ No
☐ Yes → What level? ☐ high school
☐ college (2 or 4 yr.)
☐ graduate school (law or medical school, masters program or PhD)
6. Do you work outside the home (UTMB participants only)
☐ No
☐ Yes → How many hours do you work? ☐ less than 15 hours per week
☐ 16–34 hours per week
☐ 35 or more hours per week
7. Do you have an exercise program?
☐ No, I don't have an exercise program.
☐ Yes → What type of exercise do you do? ☐ bicycling ☐ jogging/high impact aerobics
☐ treadmill/walking/low impact aerobics ☐ swimming/water aerobics
☐ lifting weights ☐ other Please write in.
8. IN THE LAST _____ MONTHS, how many times a week have you usually exercised?
☐ do not usually exercise ☐ 1–2 times per week
☐ less than once a week ☐ 3 or more times per week
9. IN THE LAST _____ MONTHS, when you have exercised, how long did you usually spend?
☐ do not usually exercise ☐ 20–30 minutes ☐ more than 45 minutes
☐ less than 20 minutes ☐ 31–45 minutes
10. IN THE LAST _____ MONTHS, have you had a urinary tract infection?
☐ No
☐ Yes → How many have you had? ☐ none ☐ 1 ☐ 2 ☐ 3 ☐ 4 or more
11. Have you taken an antibiotic in the LAST _____ MONTHS?
☐ No
☐ Yes → What was the name of this antibiotic? Please write in.
12. IN THE LAST _____ MONTHS, how many cigarettes did you smoke per day?
☐ not at all ☐ about 1 pack per day
☐ less than 1 cigarette per day ☐ about 1 1/2 packs per day
☐ 1–5 cigarettes per day ☐ 2 or more packs per day
☐ about 1/2 pack per day
13. During the PAST _____ MONTHS, on about how many different days did you have one or more drinks of beer, wine or liquor? (A “drink” is a glass of wine, a bottle or glass of beer, a wine cooler, a shot of liquor, or a mixed drink.)
☐ not at all ☐ 2 or 3 days a month ☐ 4–5 days a week
☐ once or twice ☐ Once a week ☐ every day
☐ 3–4 days in the past 3 months ☐ 2–3 days a week
☐ About once a month

14. Think of all the times you have a drink during the PAST _____ MONTHS. How many cans of beer, glasses of wine, or drinks of liquor did you USUALLY drink each time?
- | | |
|-------------------------|---|
| ☐ 9 | ☐ 4 |
| ☐ 8 | ☐ 3 |
| ☐ 7 | ☐ 2 |
| ☐ 6 | ☐ 1 |
| ☐ 5 | ☐ less than 1 can of beer, wine, or drink of liquor |
15. On about how many days did you have 5 or more drinks of beer, wine, or liquor on the same occasion during the PAST _____ MONTHS?
- | | |
|------------------------------------|--|
| ☐ never | ☐ 2 or 3 days a month |
| ☐ once | ☐ Once a week |
| ☐ 2-3 times | ☐ twice a week |
| ☐ 4-5 times | ☐ more than twice a week |
| ☐ Once a month | |

SECTION 2:

These questions ask about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

- In general, would you say your health is:
☐ excellent ☐ very good ☐ good ☐ fair ☐ poor
- Compared to one year ago, how would you rate your health in general now?
☐ much better now than one year ago ☐ somewhat worse now than one year ago
☐ somewhat better than one year ago ☐ much worse now than one year ago
☐ about the same
- 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 (mark one number on each line)?

ACTIVITIES

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

- During the past week, have you had any of the following problems with your work or other regular daily activities as a result of your physical health (mark one number on each line)?

	YES	NO
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Were limited in the kind of work or other activities	☐	☐
d. Had difficulty performing the work or other activities (for example, it took extra effort)	☐	☐

- During the past week, 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) (mark one number on each line)?

	YES	NO
a. Cut down the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Didn't do work or other activities as carefully as usual	☐	☐

- During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐ not at all ☐ slightly ☐ moderately ☐ quite a bit ☐ extremely

- How much bodily pain have you had during the past 4 weeks?

☐ none ☐ very mild ☐ mild ☐ moderate ☐ severe ☐ very severe



8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ not at all ☐ slightly ☐ moderately ☐ quite a bit ☐ extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please fill in the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?.....	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?.....	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?.....	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?.....	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?.....	☐	☐	☐	☐	☐	☐
f. Have you felt down hearted and blue?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. How much of the time, during the past FOUR WEEKS, has your HEALTH limited your social activities (like visiting with friends or close relatives)?

☐ all of the time ☐ some of the time
☐ most of the time ☐ a little of the time
☐ a good bit of the time ☐ none of the time

11. How TRUE or FALSE is each of the following statements for you?

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick easier than other people.....	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know.....	☐	☐	☐	☐	☐
c. I expect my health to get worse.....	☐	☐	☐	☐	☐
d. My health is excellent.....	☐	☐	☐	☐	☐

SECTION 3:

This section asks about your sexual activities and attitudes. Remember, everything you report is confidential.

1. In the PAST _____ MONTHS, how frequently have you had sexual intercourse?

☐ every day ☐ several times per month ☐ not at all
☐ several times a week ☐ less than 1 time per month

2. In the PAST _____ MONTHS, how many different sexual partners have you had?

☐ only 1 ☐ 2 ☐ 3 ☐ 4 or more

3. IN THE PAST _____ MONTHS, have you had a sexually transmitted disease such as gonorrhea, trich, chlamydia, syphilis, herpes, or warts?

☐ No

☐ Yes

→ How many have you had? ☐ none
☐ 1
☐ 2
☐ 3
☐ 4 or more

4. When you had sex WITH YOUR REGULAR PARTNER OR SPOUSE in the PAST _____ MONTHS, how often were condoms used?

☐ never ☐ often ☐ every time
☐ sometimes ☐ almost every time

5. The LAST TIME you had sex WITH YOUR REGULAR PARTNER OR SPOUSE, did your partner use a condom?

☐ No ☐ Yes

6. In the PAST _____ MONTHS, how much of the time was a condom used when you had sexual intercourse with someone who was NOT your steady partner or spouse?

- ☐ I did NOT have sex with someone who was NOT my steady partner or spouse
☐ Never used condoms
☐ Sometimes used condoms
☐ Often used condoms
☐ Almost everytime used condoms
☐ Every single time we had sex, a condom was used

7. How important is it to you, to NOT be pregnant at this time?

- ☐ very important ☐ not very important
☐ important ☐ not important at all
☐ somewhat important

This next series of questions asks about your attitudes and past use of condoms. Remember, your answers to these questions will be confidential.

1. How important is it for you to simultaneously use both a prescription method of contraception (to protect against pregnancy) and condoms (to protect against sexually transmitted disease) each time you have intercourse?

- ☐ very important ☐ not very important
☐ important ☐ not important at all
☐ somewhat important

2. Compared to other people you know, what do you think your chances are of getting a sexually transmitted disease (chlamydia, gonorrhea, or trichomonas) in the future if you don't use a condom?

- ☐ much lower ☐ higher
☐ lower ☐ much higher
☐ same chances as others

3. Compared to other people you know, what do you think your chances are of getting the AIDS virus in the future if you don't use a condom?

- ☐ much lower chances ☐ higher
☐ lower ☐ much higher
☐ same as others

4. How worried are you that you might have a sexually transmitted disease in your body now?

- ☐ very worried ☐ not very worried
☐ worried ☐ not worried at all
☐ somewhat worried

5. How worried are you that you could or might get a sexually transmitted disease in the future?

- ☐ very worried ☐ not very worried
☐ worried ☐ not worried at all
☐ somewhat worried

6. How worried are you that you might have the AIDS virus in your body now?

- ☐ very worried ☐ not very worried
☐ worried ☐ not worried at all
☐ somewhat worried

7. How worried are you that you might get AIDS someday?

- ☐ very worried ☐ not very worried
☐ worried ☐ not worried at all
☐ somewhat worried

Mark how much do you agree or disagree with each of the following statements:

	Disagree Strongly	Disagree	In the Middle	Agree	Agree Strongly
1. Condoms are an effective method of birth control.	☐	☐	☐	☐	☐
2. The condom is a highly satisfactory form of contraception.	☐	☐	☐	☐	☐
3. I think condoms are an excellent means of contraception.	☐	☐	☐	☐	☐
4. Condoms are unreliable.	☐	☐	☐	☐	☐
5. Condoms do not offer reliable protection.	☐	☐	☐	☐	☐
6. The use of condoms can make sex more stimulating.	☐	☐	☐	☐	☐
7. Condoms ruin the sex act.	☐	☐	☐	☐	☐
8. Condoms are uncomfortable for both partners.	☐	☐	☐	☐	☐
9. Condoms are a lot of fun.	☐	☐	☐	☐	☐
10. Use of a condom is an interruption of foreplay.	☐	☐	☐	☐	☐
11. Men who suggest using a condom are really boring.	☐	☐	☐	☐	☐
12. If a couple is about to have sex and the man suggests using a condom, it is less likely that they will have sex.	☐	☐	☐	☐	☐
13. Women think men who use condoms are jerks.	☐	☐	☐	☐	☐
14. A woman who suggests using a condom does not trust her partner.	☐	☐	☐	☐	☐
15. People who suggest condom use are a little bit geeky.	☐	☐	☐	☐	☐
16. When I suggest using a condom I am almost always embarrassed.	☐	☐	☐	☐	☐
17. It is really hard to bring up the issue of using condoms to my partner.	☐	☐	☐	☐	☐
18. It is easy to suggest to my partner that we use a condom.	☐	☐	☐	☐	☐
19. I'm comfortable talking about condoms with my partner.	☐	☐	☐	☐	☐
20. I never know what to say when my partner and I need to talk about condoms or other protection.	☐	☐	☐	☐	☐
21. It is very embarrassing to buy condoms.	☐	☐	☐	☐	☐
22. When I need condoms I often dread having to get them.	☐	☐	☐	☐	☐
23. I don't think that buying condoms is awkward.	☐	☐	☐	☐	☐
24. It would be embarrassing to be seen buying condoms in a store.	☐	☐	☐	☐	☐
25. I always feel really uncomfortable when I buy condoms.	☐	☐	☐	☐	☐

In the PAST _____ MONTHS, mark how many times each of the following happened?

	Never	1-2	3-5	6-9	10 or more
26. How many times. . .					
a. have you bought condoms?	☐	☐	☐	☐	☐
b. has your partner bought condoms?.....	☐	☐	☐	☐	☐
c. have you bought condoms together?	☐	☐	☐	☐	☐
d. have you wanted your partner to use a condom, but did NOT ask?.....	☐	☐	☐	☐	☐
e. have you ASKED your partner to use a condom?.....	☐	☐	☐	☐	☐
f. have you refused to have sex because you or your partner did NOT have a condom?.....	☐	☐	☐	☐	☐
g. Have you discussed with a partner using condoms to prevent an STD or HIV infection?	☐	☐	☐	☐	☐

These questions ask about your menstrual cycle and the pain associated with menstruation.

1. Thinking about the LAST _____ MONTHS, how many days does your menstrual bleeding last each month?

① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ ○ other

2. During the PAST _____ MONTHS, how many days were in between your menstrual cycles (first day of one to the first day of the next)?

DAYS										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

3. Please read each of the four statements below. Pick the one statement that best describes the pain and discomfort that you have experienced during your LAST _____ menstrual bleedings.

- ☐ My menstruation is not painful and does not affect my daily activity.
- ☐ My menstruation is mildly painful, but it seldom affects my daily activity. I may or may not have to take something for this pain.
- ☐ My menstruation is moderately painful and I usually take something for this pain so that I don't miss school, work, or my other activities.
- ☐ My menstruation is severely painful despite my taking medication for this pain. I usually have other symptoms such as nausea, vomiting, diarrhea, headache, or fatigue.

4. During the LAST _____ MONTHS, on average, how many days does the pain usually last?

☐ no pain ☐ ① ☐ ② ☐ ③ ☐ ④ ☐ ⑤ ☐ 6 or more days

5. Please rate the degree of pain you have experienced during the last _____menstruations by making a mark on the line below.

A horizontal line with 20 small circles representing discrete points of pain intensity. The left end is labeled "no pain at all" and the right end is labeled "unbearable pain".

OFFICE USE ONLY										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

6. During the LAST _____ MONTHS, have you missed any days at work because of pain experienced during your periods?

☐ no ☒ yes **How many days?**

	0	1	2	3	4	5	6	7	8	9
--	---	---	---	---	---	---	---	---	---	---

7. For each of the 24 items below please indicate using the following scale, how often you have had the experience in the LAST _____ MONTHS. Record your answers in the space provided.

- a. **I feel irritable, easily agitated, and am impatient a few days *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- b. **I have cramps that *begin* on the first day of my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- c. **I feel depressed for several days *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- d. **I have abdominal pain or discomfort which begins one day *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- e. **For several days *before* my period I feel exhausted, lethargic, or tired.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- f. **I only know that my period is coming by looking at the calendar.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- g. **I take a prescription drug for the pain *during* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- h. **I feel weak and dizzy *during* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- i. **I feel tense and nervous *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- j. **I have diarrhea *during* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- k. **I have backaches several days *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

7. Continued:

1. **I take aspirin for the pain *during* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- m. **My breasts feel tender and sore a few days *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- n. **My lower back, abdomen, or the inner sides of my thighs *begin* to hurt or be tender on the first day of my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- o. ***During* the first day or so of my period, I feel like curling up in bed, using a hot water bottle on my abdomen, or taking a hot bath.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- p. **I gain weight *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- q. **I am constipated *during* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- r. ***Beginning* on the first day of my period, I have pains which may diminish or disappear for several minutes and then reappear.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- s. **The pain I have with my period is not intense, but a continuous dull aching.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- t. **I have abdominal discomfort for more than one day *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- u. **I have backaches which *begin* the same day as my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- v. **My abdominal area feels bloated for a few days *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- w. **I feel nauseous *during* the first day or so of my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always
- x. **I have headaches for a few days *before* my period.**
☐ Never ☐ Rarely ☐ Sometimes ☐ Often ☐ Always

The final question describes two different ways women may experience pain with their menstrual periods. Please read each of the two descriptions and mark the type most closely experienced by you.

○ TYPE 1

The pain begins on the first day of menstruation, often coming within an hour of the first signs of menstruation. The pain is most severe the first day and may or may not continue on subsequent days. Felt as spasms, the pain may lessen or subside for awhile and then reappear. A few women find this pain so severe as to cause vomiting, fainting or dizziness; some others report that they are most comfortable in bed or taking a hot bath. This pain is limited to the lower abdomen, back and inner sides of the thighs.

○ TYPE 2

There is advanced warning of the onset of menstruation during which the woman feels an increasing heaviness, and a dull aching pain in the lower abdomen. This pain is sometimes accompanied by nausea, lack of appetite, and constipation. Headaches, backaches, and breast pain are also characteristic of this type of menstrual discomfort.

NURSING ASSESSMENT

TODAY'S DATE											
	0	1									
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3							
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	

SUBJECT NUMBER											
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	U	W									

Visit

- ☐ Initial
☐ 3 month
☐ 6 month
☐ 12 month
☐ 18 month
☐ 24 month

Method of completion

- ☐ Person
☐ Phone

SECTION 1

PLEASE COMPLETE THESE QUESTIONS ONLY AT THE INITIAL VISIT

1. Recruitment site

- ☐ UTMB ☐ WHMC

2. Date to start contraceptive:

DATE											
	0	1									
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3							
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	

3. What is patient's date of birth?

DATE											
	0	1									
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3							
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	

4. Race/ethnicity by patient report

- ☐ Caucasian ☐ Other
☐ African-American
☐ Mexican or Mexican-American

Please write in.

5. What is the month, day, and year of the last PAP smear?

DATE											
	0	1									
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3							
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	
	0	1	2	3	4	5	6	7	8	9	

6. Please indicate any of the following conditions that were reported in the H/P:

- | | |
|--|--|
| ☐ Depression | ☐ Migraines |
| ☐ Seizures | ☐ Diabetes |
| ☐ Blood clots in veins | ☐ Liver disease |
| ☐ High blood pressure | ☐ Gall bladder disease |

7. Gravidity

- ☐ None ☐ 2 ☐ 4 or more
☐ 1 ☐ 3

8. Parity

- ☐ None ☐ 2 ☐ 4 or more
☐ 1 ☐ 3

9. Number of elective abortions.

- ☐ None ☐ 2 ☐ 4 or more
☐ 1 ☐ 3

10. Number of spontaneous abortions.

- ☐ None ☐ 2 ☐ 4 or more
☐ 1 ☐ 3

STRUCTURED INTERVIEW

“These next questions are about common medical side-effects that some women experience with hormonal methods of birth control.” Use the words at the initial visit, “Before you begin taking your chosen method of contraception, I want to see if you have experienced any of these things in the last 3 months.” At each of the follow-up visits use the words, “IN the LAST _____ MONTHS have you experienced any of these. In addition, for those side-effects you have experienced, we are interested in knowing whether the problem has stopped.”

1. How long have you been taking your contraceptive? (F/U VISITS ONLY)

- ☐ 3 months ☐ 6 months ☐ 12 months ☐ 18 months ☐ 24 months

PLEASE DO NOT WRITE IN THIS AREA

301944

2. Have you experienced... (Mark all that apply)

If yes, has this resolved?

☐ I haven't experienced any side-effects

YES

NO

YES

NO

Menstrual bleeding more than 20 days in a row ☐

Bleeding between periods ☐

No menstrual bleeding ☐

Headaches ☐

Nervousness ☐

Nausea ☐

Dizziness ☐

Breast tenderness ☐

Decrease in appetite ☐

Increase in appetite ☐

Weight gain ☐

Diminished sexual drive ☐

Loss of scalp hair ☐

Hair growth on upper lip of chin ☐

Acne ☐

Other, please specify _____ ☐

3. In the PAST _____ Months, how frequently have you had headaches? (mark one)

- ☐ Never ☐ 4-6 times a week
- ☐ 1-2 times a month ☐ 7-10 times a week
- ☐ 1-3 times a week ☐ More than 10 times a week

➤ Are you still experiencing headaches? ☐ No ☐ Yes

4. In the PAST _____ Months, how frequently have you had dizzy spells? (mark one)

- ☐ Never ☐ 4-6 times a week
- ☐ 1-2 times a month ☐ 7-10 times a week
- ☐ 1-3 times a week ☐ More than 10 times a week

➤ Are you still experiencing dizzy spells? ☐ No ☐ Yes

5. In the PAST _____ Months, did you feel sad, down, and/or blue much of the time? (mark one)

- ☐ No ☐ Yes ➤ Are you still feeling sad, down, and/or blue much of the time? ☐ No ☐ Yes

6. In the PAST _____ Months, did you feel tired much of the time?

- ☐ No ☐ Yes ➤ Are you still feeling tired much of the time? ☐ No ☐ Yes

7. In the PAST _____ Months, how is your complexion? Have you had a change in acne?

- ☐ I don't have any problem with acne ☐ Improving (less acne) in the last 3/6 months
- ☐ No change in my acne ☐ Worst (more acne) in the last 3/6 months

8. In the PAST _____ Months, have you experienced pain frequently when having intercourse?

- ☐ No ☐ Yes ➤ Does pain occur on insertion? ☐ Yes ☐ No
- Does pain occur during thrusting? ☐ Yes ☐ No
- Are you still experiencing this pain? ☐ Yes ☐ No

ASK THESE QUESTIONS ONLY AT THE 3 MONTH VISIT

1. Did you read and understand the Patient Package Information Sheets that you were given at your first visit?

- ☐ Read and understood all ☐ Read and understood little or none
- ☐ Read and understood some ☐ Did not read any of the material given to me

2. At your first visit, did you receive adequate information about your chosen method of birth control?

- ☐ Yes ☐ No

LAB AND TEST RESULTS

These next questions are recorded from visit as well as lab or test results.

1. Weight

Pounds										
(1)	1	2	3	4	5	6	7	8	9	
(2)	1	2	3	4	5	6	7	8	9	
(3)	1	2	3	4	5	6	7	8	9	

2. Blood Pressure

Systolic										
(1)	1	2	3	4	5	6	7	8	9	
(2)	1	2	3	4	5	6	7	8	9	
(3)	1	2	3	4	5	6	7	8	9	

Diastolic										
(1)	1	2	3	4	5	6	7	8	9	
(2)	1	2	3	4	5	6	7	8	9	
(3)	1	2	3	4	5	6	7	8	9	

3. Bone density

L1-L4 BMD										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Total FN BMD										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

4. Plasma lipid levels

Total										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

HDL										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Triglycerides										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

LDL										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

5. Colter profile

HGB										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

HCT										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

6. Pap smear (Initial, 12, and 24 months visits only)

	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

- | | |
|---------|---------------------------|
| 1 WNL | 6 HSIL |
| 2 WNL-D | 7 Squamous cell carcinoma |
| 3 ASCUS | 8 Adenocarcinoma |
| 4 AGUS | 9 Malignant Neoplasm |
| 5 LSIL | 10 No diagnosis made |

7. Gonorrhea

☐ negative ☐ positive

8. Chlamydia

☐ negative ☐ positive

9. Syphilis

☐ negative ☐ positive

10. Record skinfold measurements

Triceps										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

MAC										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Subscapular										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

WHR										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

11. Record calculated caloric intake, grams of fat, protein, and carbohydrate.

Caloric intake (kcal)										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Carbohydrate										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Protein										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Fat										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

12. Record menstrual calendar data

Number of bleeding runs										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of fourth bleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of first nonbleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of first bleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of fifth bleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of second nonbleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of second bleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of sixth bleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of third nonbleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of third bleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of fourth nonbleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Number of nonbleeding intervals										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Number of nonbleeding days										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of fifth nonbleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Number of bleeding days										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Longest bleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Length of sixth nonbleeding run										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Number of spotting days										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Longest nonbleeding interval										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

PILL USERS ONLY

Number of pills remaining in returned pill packs

Pack #										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Number remaining										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Pack #										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Number remaining										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Pack #										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Number remaining										
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Pack #										
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Number remaining										
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Pack #										
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Number remaining										
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Pack #										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Number remaining										
	0	1	2	3	4	5	6	7	8	9
	0	1	2	3	4	5	6	7	8	9

Please rate each subject's hirsutism using the following scale. This is to be a visual rating.

Site	Grade	Definition
1. Upper Lip	① ② ③ ④	A few hairs at outer margin. A small mustache at margin. A mustache extending halfway from outer margin. A mustache extending to mid-line.
2. Chin	① ② ③ ④	A few scattered hairs. Scattered hairs with small concentrations. Complete cover, light. Complete cover, heavy.
3. Chest	① ② ③ ④	Circumareolar hairs. With mid-line hair in addition. Fusion of these areas, with three-quarter cover. Complete cover.
4. Upper back	① ② ③ ④	A few scattered hairs. Rather more, still scattered. Complete cover, light. Complete cover, heavy.
5. Lower back	① ② ③ ④	A sacral tuft of hair. With some lateral extension. Three-quarter cover. Complete cover.
6. Upper abdomen	① ② ③ ④	A few mid-line hairs. Rather more, still mid-line. Half cover. Full cover.
7. Lower abdomen	① ② ③ ④	A few mid-line hairs. A mid-line streak of hair. A mid-line band of hair. An inverted V-shaped growth.
8. Arm	① ② ③ ④	Sparse growth affecting not more than a quarter of the limb surface. More than this: cover still incomplete. Complete cover, light. Complete cover, heavy.
9. Forearm	① ② ③ ④	Complete cover of dorsal surface; light. Complete cover of dorsal surface; medium-light. Complete cover of dorsal surface; heavy. Complete cover of dorsal surface; medium-heavy.
10. Thigh	① ② ③ ④	Sparse growth affecting not more than a quarter of the limb surface. More than this: cover still incomplete. Complete cover, light. Complete cover, heavy.
11. Leg	① ② ③ ④	Sparse growth affecting not more than a quarter of the limb surface. More than this: cover still incomplete. Complete cover, light. Complete cover, heavy.

Total =

Total Score =



Discontinuation Assessment

Today's date: _____

Subject Number: _____

Discontinuation Date: _____

The interviewer needs to remind subjects that as we told them at the time of discontinuing their chosen method, we are calling to assess their current status. This phone interview will only take a few minutes and while some of the questions may be considered sensitive, all collected information will remain confidential. We really appreciate their time in collecting these data.

1. Are you currently pregnant?

___ yes

___ no---> **How important is it to you, to NOT be pregnant at this time?**

___ very important

___ important

___ somewhat important

___ not very important

___ not important at all

2. Are you currently using another hormonal method of contraception?

___ No

___ Yes---> **What is the name of the method you are using?**

___ pills _____

___ Depo-Provera

___ IUD

-----> **How long have you been using this method?__ months**

3. How satisfied have you been with this method? Or if not using a hormonal method, " How satisfied have you been not using a hormonal method of contraception?"

___ extremely dissatisfied

___ not satisfied

___ somewhat satisfied

___ satisfied

___ extremely satisfied

4. Do you think your current contraceptive method is

___ easier than other methods you have tried

___ more difficult than other methods you have tried

___ the same difficulty as other methods

5. How easy has it been for you to use this method of contraception?

___ very easy

___ easy

___ somewhat easy

___ not very easy

___ not at all easy

- _____ haven't experienced any side-effects

			If yes, has this resolved?	
	Yes	No	Yes	No
☐ menstrual bleeding more than 20 days in a row	☐	☐	☐	☐
☐ bleeding between periods	☐	☐	☐	☐
☐ no menstrual bleeding	☐	☐	☐	☐
☐ headaches	☐	☐	☐	☐
☐ nervousness	☐	☐	☐	☐
☐ nausea	☐	☐	☐	☐
☐ dizziness	☐	☐	☐	☐
☐ breast tenderness	☐	☐	☐	☐
☐ decrease in appetite	☐	☐	☐	☐
☐ increase in appetite	☐	☐	☐	☐
☐ weight gain	☐	☐	☐	☐
☐ diminished sexual drive	☐	☐	☐	☐
☐ loss of scalp hair	☐	☐	☐	☐
☐ hair growth on upper lip of chin	☐	☐	☐	☐
☐ acne	☐	☐	☐	☐
☐ other, please specify _____	☐	☐	☐	☐

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