A. INITIAL VISIT

1. Initial history
   a. Relevant family history to include breast or uterine cancer, history of myocardial infarct, stroke, or thromboembolitic disorder before age 50, diabetes or other chronic or serious disorder, such as hypertension.
   b. Gynecologic history, including age of menarche, date of last normal menstrual period, history of dysmenorrhea, hypermenorrhea, oligomenorrhea, polymenorrhea, intermenstrual bleeding, post-coital bleeding, dyspareunia, previous history of pelvic infection, sexually transmitted diseases, or vaginal discharge.
   c. Obstetric history covering gravidity, parity, and pregnancy outcome, i.e., number of abortions (spontaneous or induced), premature deaths, living children, and intervals between pregnancies. Specific complications of pregnancies should be recorded.
   d. Medical and surgical history - special emphasis on systemic review:
      1) Cardiovascular history
      2) Thromboembolic disease
      3) Hypertension (essential or malignant)
      4) Vascular or migraine headaches
      5) Neurologic/visual disturbances
      6) Metabolic history
         a) Diabetes, prediabetes, or gestational diabetes
         b) Hepatic disease
         c) Hyperlipidemia
         d) Thyroid disorders
      7) Cancer (potential or confirmed) history
         a) Diagnosed or suspected breast cancer
         b) Diagnosed or suspected reproductive cancer
      8) Neurologic history
         a) Depression
         b) Epilepsy
      9) Hemopoietic history
         a) Hemoglobinopathies (e.g., Sickle cell trait or disease, thalassemia)
         b) Blood dyscrasias
      10) Genito-urinary history
         a) Renal disease
         b) UTI
      11) Previous contraceptive use and any problems with method.
      12) Social history including:

a) Sexual history including partner history of

(1) injectable drug use

(2) multiple partners

(3) risk history for STDs and HIV

(4) bisexuality

b) History of physical abuse

c) History of substance use/abuse

13) Relevant socio-economic data.

14) Immunization for rubella, tetanus, hepatitis B, and Human Papilloma Virus.

15) DES history if born prior to 1970.

16) Nutritional history.

17) Allergies.

18) Current medications.

2. Client education

During the initial visit, all women receiving family planning services must be provided information on the following, either verbally or in writing, when appropriate. Presentation of client education should be appropriate for client's age, knowledge, language, and socio-cultural background.

a. Brochure of family planning services is included in packet distributed to all initial clients. Staff answers any questions that the client poses either verbally or on history sheet/client assessment checklist.

b. Purpose and sequence of clinic procedure

Staff explains to client what will happen from the time of arrival to the time of leaving, including waiting time, lab tests, and medical exams. Results of routine tests (blood pressure, blood, and urine) are explained by designated staff. Questions are encouraged and answered by staff.

c. Basic female and male reproductive anatomy and physiology.

Reproductive Anatomy: Designated staff discusses basic anatomy and physiology in reference to birth control methods and answers questions indicated on the history form. Practitioner gives more detailed information during exams. Male and female reproductive anatomy and physiology diagrams are included in the Family Planning Program brochure.

Pelvic exam and Pap smear procedures are explained.

d. Breast self-exam. - "Beginning in their 20s, women should be told about the benefits and limitations of breast self-examination (BSE). The importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of the periodic health examination. It is acceptable for women to choose not to do BSE or to do BSE irregularly." (American Cancer Society Guidelines for Breast Cancer Screening: Update 2003)

e. Methods of contraception

Specific factors concerning any method's safety (potential side effects or complications), effectiveness, acceptability to client and partner, correct usage, and how to discontinue use must be explained to client.

1) Temporary

a) Abstinence

b) Natural family planning methods

c) Spermicides: Jelly, Foam, Suppository, Film, Sponge

d) Barrier: Diaphragm, Male and female condom

e) FDA approved hormonal contraceptives, including hormonal implants

f) IUD

g) Emergency contraception

2) Permanent:

Male and female sterilization.

f. Rubella immunity: Importance of and how to achieve.

g. DES: use by client's mother (prior to 1970); implications for client

h. HIV risk assessment/AIDS education

All clients receive information about HIV and about behaviors that are high-risk for HIV infection. Referrals are available for counseling and testing sites as needed. (See HIV/AIDS prevention/risk reduction policy.)

i. Client rights and responsibilities

j. Emergency resources

k. Nutrition information from the history form should be discussed and questions answered. The importance of folic acid intake should be discussed/handouts given to all clients. DMPA users must be counseled about increasing calcium intake and about the black box warning issued by Pfizer.

l. Information about the vaccine for Human Papilloma Virus (HPV) for women 13 – 26.

3. Initial physical examination

The following are guidelines for the periodic health examination. Guidelines should never be a substitute for sound clinical judgment. References used in preparing these guidelines include: 1. American College of Obstetrics and Gynecology (ACOG), Primary and Preventive Care: Periodic Assessments, Committee Opinion No. **452**, December 200**9** and The Initial Reproductive Health Visit, Committee Opinion 335, May 2006; 2. American Cancer Society (ACS), Guidelines for Breast Cancer Screening: Update 2003

a. General overall appearance – All clients

b. Height, weight, and Body Mass Index (BMI) – All clients

c. Blood pressure – All clients

d. Thyroid – ACOG recommends starting at age 19

f. Clinical Breast Exam – ACOG recommends starting at age 19;

g. Heart – There is no recommendation for or against auscultation of the heart

h. Lungs - There is no recommendation for or against auscultation of the lungs

i. Abdomen – ACOG recommends starting at age 19

j. Extremities for varicosities and signs of phlebitis – There is no recommendation for or against examining extremities

k. Pelvic examination (including visualization and inspection of external genitalia, vagina, and cervix, and bimanual exam) – ACOG recommends starting at age **21, unless indicated by medical history at age <21.**

l. Rectal examination, as indicated by medical history or findings on pelvic exam

4. Laboratory testing

a. The following procedures are to be done, according to the screening guidelines outlined in the Pap Smear Screening and Follow-up protocol and the Laboratory protocol, unless written results from another facility are available:

1) Pap smear, as per **ACOG** guidelines

Repeat according to Pap Smear Screening and Follow up protocol

2) Chlamydia screening for all clients <25 years

Must be done under the following circumstances:

a) All women <25 years of age, **unless client declines (please document why)**

b) Prior to (within 60 days and including a GC test) **or at the time of IUD insertion**

c) Symptomatic of cervicitis or pelvic infection (should include GC test)

d) When a client requests such screening

e) Contact to STD

Must be offered to the following:

a) Positive chlamydia test in the past 12 months without a subsequent negative test.

b) Multiple sexual (≥2) partners or a new sexual partner(s) in the last **60** days

c) Women with a history of gonorrhea/PID in the previous year (should include GC test)

d) Anyone being treated for any other STD

b. Other laboratory tests, as indicated:

1) Pregnancy test

2) Microscopic examination of wet mounts or spun urines

3) Rubella screening

4) Glucose screening for women with history of gestational diabetes.

5) Serology test for syphilis:

Must be done or a referral made if following conditions exist:

a) Client who reports having been exposed to, or suspects she may be infected with syphilis.

b) Client with previous positive serologic test for syphilis with incomplete or unknown treatment (do VDRL).

c) Client with undiagnosed genital lesion, suspicious rashes, or other physical signs consistent with syphilis.

d) Client request.

e) Client with a positive HIV or gonorrhea test.

f) Depending on other risk factors, clients with condyloma, herpes, or Chlamydia should be offered a serology test for syphilis.

5. Provision of contraceptive methods

   a. Abstinence.

   b. Natural family planning.

   c. Foam, creams, jellies, suppositories, sponges, film.

   d. Barrier: Diaphragm, Condoms, both male and female.

   e. Hormonal contraceptives, including hormonal implant.

   f. Intrauterine devices.

   g. Emergency contraception.

   h. Counseling for permanent methods: Male and female sterilization

6. Post-examination interview

   a. Following the physical examination (done as indicated), the client should have an interview with an appropriately trained member of the health team. The interviewer should be able to answer the client's questions. The following should be covered during the interview:

      1) Interpretation of clinical findings including history, physical examination (as appropriate) and laboratory results. If the client has an infection, the practitioner provides verbal information and appropriate brochure with explanation of infection and treatment procedures. Current handouts or pamphlets on vaginitis, cervicitis, condylomata, herpes, PID, chlamydia, and other sexually transmitted diseases should be available upon request or as indicated by client interest.

      2) Answer questions about the contraceptive method or any part of the procedure up to that point.

      3) Provide oral and written information on the following:

         a) Directions for the chosen method of contraception and/or appropriate therapeutics

         b) Name of the type of pill, diaphragm, or IUD used; removal date for IUD or Implanon

         c) Potential side effects and complications for the method used, and what the client should do if any occur

         d) How to discontinue prescription methods of contraception

b. Give written information of the following:

1) Office hours and telephone number

2) Reinforcement of emergency care and side effect information

3) Telephone number and location where emergency services can be obtained

c. Special counseling, as indicated, regarding:

1) Future planned pregnancies (see Preconception Counseling **information on page 9 of this section)**

2) Management of current pregnancy

3) Sterilization

4) Other individual problems or concerns (e.g., genetic, nutritional, sexual)

5) All new adolescent clients are screened for social support and offered appropriate counseling referrals. Parental involvement is encouraged. Particular emphasis is placed on STD risk reduction strategies. If relevant history of sexual abuse is reported by a client under the age of 18 yrs., this must, by law, be referred to Social Services or law enforcement. (See Adolescents Section X) **Fewer requirements for the physical exam for adolescents <21 years will allow more time to be spent on adolescent counseling.**

d. Nutrition education

1) Nutrition needs relative to birth control methods are discussed as appropriate. Nutrition protocols are available to help with counseling.

2) RN/NP should discuss nutrition as relevant to medical problems (obesity, anemia, anorexia-bulimia) and offer appropriate referrals for additional counseling/treatment.

e. Inform the client about the return visit schedule

1) Intake staff and practitioner discuss with the client the importance of periodic check-ups, how to obtain additional supplies, how to contact the clinic in between appointments, and what to do in case of a medical emergency.

2) Educate client about importance of follow-up.

a) Make appropriate referrals for any needed medical service not provided through the clinic. (See Referral and Follow-Up Section V).

b) Client education is documented in the chart.

B. REVISIT

1. PRN, if the lab tests indicate necessity (positive GC, abnormal Pap smear, positive chlamydia, etc.) or for subsequent boosters of HPV vaccine.
2. Oral contraceptive/contraceptive patch/contraceptive vaginal ring clients: 3 months after initial visit for all first-time hormonal contraceptive users; subsequently annually, unless client's risk status indicates more frequent evaluations. Established pill clients who change pill brand do not need a 3 month pill check. The next time the client comes in or calls, she should be questioned about how she is doing on the new brand.
3. DMPA (Depo-Provera or Depo subQ Provera 104) clients: every 11 - 13 weeks for re-injection.
4. IUD clients: Within 3 months of insertion; then annually.

5. Diaphragm clients: Within 2-4 weeks of fitting, to check fit; then at least every 2 years
6. Implanon clients: PRN for signs of infection at insertion site, then annually;
7. As needed for any client experiencing contraceptive side effects or problems, or requiring additional information or supplies.
8. Content of revisit:
   a. Update original database in any area where changes have occurred, including changes in personal and family histories.
   b. Laboratory tests as indicated by method or client history (e.g., GC if client indicates exposure; Hematocrit if IUD client indicates excessive bleeding)
   c. Evaluation of any problem previously identified that may be unresolved.
   d. Physical exam, as indicated by method:
      1) Oral contraceptive/contraceptive patch/contraceptive vaginal ring client:
         a) Weight, if client wishes
         b) Blood pressure.
      2) Implanon clients
         a) Weight, if client wishes
         b) Blood pressure
         c) Insertion site, if indicated
      3) Depo-Provera clients:
         a) Weight, if client wishes
         b) Blood pressure at first reinjection, then annually
      4) IUD clients (2-3 months post insertion):
         a) Visualization of cervix with string check
         b) Bi-manual examination
      5) Diaphragm clients:

         Pelvic examination to assure proper placement and fit within one month of fitting.
   e. Discussion with the client about any problems that may relate to the chosen method.
   f. Specific information to be evaluated, by method (See specific method protocol):
   g. Treatment, referral or change of method as required.
   h. Education, as required.
      1) Infection check: Provide information regarding cause, treatment, and involvement of partner.
      2) Method Problem: After clinician has determined seriousness of problem, clinician or other staff should educate regarding alternative choices of birth control as indicated. Risks and side effects of given method shall be reviewed, as well as emergency procedures, to ensure client understanding.
      3) Pregnancy Test: Client shall fill out request form, which is reviewed by appropriate staff. Counseling and referral shall be offered regarding options, including prenatal

care, adoption, and termination for positive test result, and infertility or use of method counseling for negative test results, as appropriate.

4) Other: At any visit staff should assess client's needs for information, education, and counseling.

C. ANNUAL VISIT

(Or every 24 months services as indicated by client method and risk factors)

1. Update of initial history/family history. (Review history and problem list for unresolved problems. Complete medical and personal history must be redone every three years.)
2. Indicated laboratory tests (e.g., Pap smear as per protocol).
3. Physical exam as indicated by method and Current ACOG guidelines.
4. Education and counseling, as indicated.

   All clients receiving family planning services will have their level of understanding assessed regarding:

   a. Chosen method of birth control - accurate understanding of method and awareness of emergency contraception.
   b. Breast Self-Exam, if client wishes, and HIV information, as appropriate.
   c. Nutrition, including information on folic acid and calcium intake.
   d. Reproductive anatomy and physiology.
   e. Preconception counseling, as indicated.
   f. Rationale for/results of lab tests.
   g. Warning signs and emergency procedures.
   h. Any informational brochures provided.
5. Education is documented in client record.

D. PROBLEM VISITS

At the time of the problem visit, there should be: (See appropriate protocol for indicated data collection, exam, treatment, and client education.)

1. Appropriate update of database.
   a. Evaluation of pre-existing problems or need for follow-up.
   b. History of new problems, if indicated.
2. Examination of the problem area and other areas, as indicated.
3. Performance of appropriate laboratory tests.
4. Change of contraceptive method, if indicated.
5. Referral for problem if unable to be resolved at this agency. (See Referral and Follow-Up Protocol)
6. Education

a. All clients shall receive information and education that ensures a thorough understanding of the findings of the visit. *Please refer to 'h' under Content of Revisit on page 7.

b. Education and counseling received is documented in client record, as are referral forms and pregnancy request forms.

E. SUPPLY ONLY VISIT

All clients shall receive the contraceptive selected at previous visit, have the opportunity to express concerns, and schedule a revisit if desired.

1. Staff will ensure that proper contraceptive prescription and education are on file in the client's record.
2. Client will be encouraged to express problems or concerns.
3. If necessary, client will speak with appropriate staff member for additional education/counseling. (This visit may then be coded as a revisit).
4. Staff should remind client of the next visit and reinforce importance and knowledge of emergency procedures.
5. Client visit will be documented as supply visit **unless there is a face to face visit with a provider (thus coded as a revisit and not a supply only visit). If there is a face to face encounter, then there will be documentation of education given, if indicated.** Contraceptives dispensed should be documented specifically, e.g., by type of pill, in all places required to comply with the Pharmacy Board and standard pharmacy practices.

F. PRECONCEPTION COUNSELING

Clients contemplating pregnancy within the next year should be given the opportunity for special counseling prior to discontinuing their method, with the objective of improving the outcome of a planned pregnancy. The following should be discussed:

1. History - an updated health history may be taken from the client, to include:
   a. Medical history, including rubella immune status, heart disease, hypertension, anemias or blood disorders, liver disease, diabetes, epilepsy.
   b. Reproductive history, including DES exposure, genital herpes, or previous pregnancy problems, risk status for HIV or Hepatitis B.
   c. Medication history
   d. Social and occupational history, including use of tobacco, alcohol, or other substances, domestic violence.
   e. Nutritional history, including the addition of 0.4 mg of folic acid/day, as recommended by the CDC in its MMWR, September 11, 1992; Vol. 41; No. RR-14
   f. Family history, including anemias or blood disorders, diabetes, or birth defects.
2. Physical exam
3. Lab tests as indicated
4. General education

a. The need for early and continuing care during pregnancy, with referral to prenatal care providers, if requested

b. The importance of good nutrition, including the addition of 0.4 mg of folic acid supplemented per day to decrease the risks of neural tube defects

c. Warnings regarding the use of tobacco, alcohol, and drugs during the preconception period as well as during pregnancy

d. Assessment of potential high risk factors, including genetic risks, with referrals as indicated

e. Counseling regarding HIV testing. Information from the CDC MMWR, July 7, 1995, Vo. 44/No. RR-7 should be shared with clients, specifically the results of the HIV Clinical Trial 076. While the standard is for all pregnant women to be tested, regardless of risk status, there are great benefits to women to know their HIV status preconceptionally.

f. Assessment of psychosocial risk factors, including lack of support system or domestic violence/sexual assault.

5. Recommendations for Stopping Birth Control Methods

a. Oral contraceptive/contraceptive patch/contraceptive vaginal ring

1) There is no evidence to recommend that a period of time elapse between the cessation of hormonal contraceptive use and initiation of a planned pregnancy.

2) Client may be advised to return for evaluation if menstrual periods do not resume six to eight weeks after cessation of these hormonal contraceptives.

b. IUD

No special recommendations

c. Depo-Provera

Since ovulation may take as long as 9-12 months to return, it is advisable to have the client plan to stop the injections up to a year before she wishes to become pregnant, and to use another method of birth control until conception is desired.

d. Implanon

No special recommendations

G. MEN'S SERVICES

Title X requires documentation of a thorough medical history for male clients.

1. The medical data on the men's record for initial and follow-up visits shall include the following:

a. Sexual history (as appropriate)

1) Maternal use of DES through 1970

2) Sexual preference

3) Review of recent sexual activity

a) Time since last sexual exposure

b) Number of/new partners in the past 60 days

c) Specific exposure sites (i.e., urethral, rectal)

d) Illness or evidence of STDs in recent partners

4) History of/risk for sexually transmitted infections, including HBV, HIV

5) Knowledge of how to do/importance of Testicular Self Exam (TSE)

b. Contraceptive history (as appropriate)

1) Methods used

2) Problems/satisfaction with methods

3) Methods requested today

c. Family history, general medical history (to include urological conditions), and review of systems

To include substance use/abuse, physical abuse, etc.

d. Medication history

1) Allergies to specific medications

2) Current medications being taken

3) History of antibiotic use in the previous two weeks

e. Reason for visit

1) Problem description

2) Symptoms

2. A physical examination must be offered initially, and at subsequent visits as appropriate. The routine physical exam could include:

a. Height, weight, and BMI

b. Blood pressure

c. Thyroid, heart, lung, extremities, breasts, abdomen, genital (more detail in f - k), and rectal as indicated (i.e., hemoccult over 50)

d. Inspection of oral mucosa, if indicated

e. Inspection of skin for rashes and lesions

f. Inspection of pubic hair for lice and nits

g. Inspection of penis, including urethral meatus, retraction of foreskin, and expression of any discharge from the urethra.

h. Inspection of scrotum including anterior and posterior scrotal walls

i. Palpation of scrotal contents

j. Palpation of inguinal area for lymphadenopathy

k. Inspection of perianal area, if indicated

l. Further examination as indicated by history or laboratory findings.

3. Laboratory tests

a. Tests for gonorrhea/chlamydia from urethra (using urine-based test), the rectum and/or oral pharynx should be done under the following circumstances (contact your lab for specifics on obtaining rectal or pharyngeal specimens):

1) History and/or findings of urethral or rectal discharge and/or dysuria

2) History of recent contact with gonorrhea/chlamydia/PID
3) Client requests a test for gonorrhea, chlamydia, or any other STD
4) Client is being treated for any other STD
5) Known multiple sexual partners or a change in sexual partners in the last 60 days (should be offered)
6) History of GC/NSU (non-specific urethritis) in the previous year

b. A serologic test for syphilis (RPR)

Please refer to the information on syphilis in the STD Section of this manual.

c. Serologic test for HIV infection

Men with known risk factors for HIV infection should be advised as to testing availability. Please refer to the HIV/AIDS Section of this manual.

4. Contraceptive education and counseling

a. Men requesting a temporary method of birth control should receive the same education and counseling specific to that method as outlined in the methods protocols.

b. Men requesting vasectomy should receive the education and counseling outlined in the sterilization policy. Give referrals for vasectomies, including No Scalpel Vasectomy (NSV) if available.

H. CLIENTS INVOLVED IN RESEARCH PROJECTS

All programs considering clinical or sociological research must adhere to the legal requirements governing human subjects research (45 CFR Part 46). There must be informed consent of the client and approval of research by a properly constituted committee of the grantee institution. Copies of the federal regulations are available from the WHU or by going to: http://www.gpoaccess.gov/cfr/index.htm

Programs must advise the Women's Health Unit in writing of research projects involving Title X clients or resources. The WHU must then forward the request to the regional Health and Human Services office and the Office of Population Affairs.

(Program Guidelines 5.5, p.6)

SUMMARY OF SERVICE REQUIREMENTS

A. INITIAL VISIT

1. Education (group or individual)
2. Financial information
3. Complete medical history
4. Weight, height, and BMI
5. Blood pressure
6. Pap smear, if indicated by screening guidelines
7. Chlamydia screening according to screening criteria
8. **Fecal occult blood screening for men (should be offered) and women (must be offered) age 50 or over**
9. Physical examination, as indicated
10. Post-exam interview
11. Supplies as needed
12. Return appointment made

B. ANNUAL VISIT

1. Update database, including medical history and financial information, as needed
2. Weight and BMI
3. Blood pressure
4. Pap smear, if indicated by screening guidelines
5. Chlamydia screening according to screening criteria
6. **Fecal occult blood screening for men (should be offered) and women (must be offered) age 50 or over**
7. Physical examination, as indicated
8. Post-exam interview/education
9. Supplies as needed
10. Return appointment made

C. REVISIT/PROBLEM VISIT

1. Update database
2. Weight, if applicable
3. Blood pressure, if applicable
4. Laboratory tests, as indicated
5. Physical exam, as indicated
6. Post interview/education

7. Supplies
8. Return appointment, as indicated

D. SUPPLY VISITS

1. Record verified for date of last examination
2. Order verified for method, e.g., type of OC, number of cycles already dispensed, and number of cycles left on prescription
3. Update on any problems or concerns

E. VISITS BY CONTRACEPTIVE METHOD

1. Oral contraceptives/contraceptive patch/contraceptive vaginal ring

   a. New to method
      3 cycles, then return for 3-month evaluation. If evaluation satisfactory, then:
      10 cycles (maximum) if method evaluation normal, or
      13-14 cycles if prescribing for extended use of oral contraceptives (12 weeks on 1 week off)

   b. Annual
      Up to 13 cycles (maximum), or
      Up to 16-17 cycles if prescribing for extended use of oral contraceptives, as above

   c. Revisits
      Individual discretion for more frequent visits may be made for special circumstances, (i.e., teens, changing eligibility status, slightly elevated B/P, heavy smoking, etc.) However, dispensing 1 or 2 cycles at a time is viewed as a barrier to continuity of method use. (If the client does not plan to refrigerate, then NuvaRing® should only be dispensed four cycles/rings at a time.)

2. DMPA (Depo Provera and Depo subQ104 Provera)

   a. Every 11 - 13 weeks for re-injection
   b. Annual visit
   c. Revisits, as needed

3. Implanon

   a. Annual visit
   b. Revisits, as needed

4. IUD

   a. New insertion
      6-12 week post-insertion exam
   b. Annual
   c. Revisits, as needed

5. Diaphragm
    a. Return within 2-4 weeks for evaluation and fit check
    b. Annual or bi-annual visit
    c. Revisits, as needed
6. Spermicide and/or condoms
    a. Annual or bi-annual visit
    b. Revisits, as needed
7. Natural family planning
    a. Annual or bi-annual visit
    b. Revisits, as needed
8. Sterilization
    a. Annual or bi-annual visit
    b. Revisits, as needed

F. PROTOCOL POLICY

1. Nurse practitioners will provide medical services according to written, signed protocols.
2. Protocols will be reviewed after additions or revisions by supervising physician and the nurse practitioner.

    Date and signature of physician and nurse practitioner(s) will be noted on protocols at review time.
3. Protocols developed by individual practitioners and physicians must be in line with the Program Guidelines for Project Grants for Family Planning Services under Section 1001, Public Health Service Act.
4. Program protocols must be reviewed by the Family Planning Program Nurse Consultant.