I. Client Selection

A. Indications – combined oral contraceptive pills (COCs) may be provided:

1. When contraindications do not exist;

2. Post-pregnancy:

   a. May begin immediately after abortion;

   b. May initiate 3-4 weeks after second trimester abortion or postpartum and non-lactating;

   c. Exercise caution in nursing women less than six months postpartum. Document discussion of potential risks/benefits such as decrease in milk supply.

B. Contraindications – refrain from providing (based on WHO Medical Eligibility Criteria)

1. History of deep vein thrombosis or pulmonary embolism; known thrombogenic mutations such as Protein C or S resistance and Factor V Leiden (WHO Medical Eligibility Criteria, 2004), or EXTENSIVE familial history of deep vein thrombosis. (Thrombosis related to either a known trauma or an IV needle is not necessarily a reason to avoid use of COCs.);

2. History of thrombotic cerebrovascular accident;

3. Vascular, coronary artery, ischemic heart disease, myocardial infarction or current angina pectoris, or history thereof;

4. Age $\geq$ 35 and smoking $\geq$ 15 cigarettes a day;

5. Hypertension: systolic $\geq$160 or diastolic $\geq$100;

6. Diabetes mellitus with clinically manifested vascular disease (diabetic nephropathy, retinopathy, neuropathy or peripheral vascular disease);

7. Known or suspected carcinoma of the breast or endometrium, or other estrogen-dependent neoplasia. COC use may be considered, in consultation with the physician, for women with a past history of breast cancer but no evidence of estrogen dependence in the cancer and no recurrence for 5 years;

8. Benign hepatic adenoma, liver cancer, or history thereof; active viral hepatitis, severe cirrhosis or markedly impaired liver function currently;

9. Migraine headaches with focal neurological symptoms (visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities);

10. Unexplained abnormal vaginal or uterine bleeding, NOT including irregular menses;

11. Planned major surgery with prolonged immobilization or any surgery on the legs;

12. Suspected pregnancy;

13. Lactation (<6 weeks postpartum).

C. Special conditions requiring further evaluation: The theoretical/proven risks generally outweigh the advantages of using the method. The patient must be provided with information regarding the way in which these conditions may add to a health risk for her. This discussion must be documented. (Based on WHO Medical Eligibility Criteria)

1. Adverse cardiovascular risk profile (see V. Management of Women with Special Conditions Requiring Further Evaluation p. 4, this protocol);

2. Active or medically treated gallbladder disease, history of COC-related cholestasis.

3. Migraine headaches without focal neurological symptoms **(visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities)** [see V. Management of Women with Special Conditions Requiring Further Evaluation p. 6, this protocol];

4. Elevated blood pressure measurements – 140-159/90-99 on three separate visits within a two week period. (See Flow Chart for Management of Clients Using Combined Oral Contraceptives Who Develop High Blood Pressure – page 6 of this protocol);

5. Age ≥35 years old and smoking <15 cigarettes per day;

6. Seizure disorder, currently taking anticonvulsants that affect liver enzymes (see V. Management of Women with Special Conditions Requiring Further Evaluation p. 7, this protocol);

II. Patient Education/Informed Consent – must include:

A. All clients choosing to use oral contraceptives must receive the following information:

1. Fact sheet on all contraceptive options available if she is a new client or is undecided as to what method she wishes to use;

2. A copy of the FDA approved detailed patient labeling pamphlet. The importance of reading the FDA pamphlet must be explained to the client.

3. Instructions on how to take the pill. (For instructions, see current Contraceptive Technology, Eighteenth Edition, pp. 438-441.)

4. Information that the effectiveness of COCs may be decreased by some medications (See Drug Interactions V.G, page 7 of this protocol).

5. The importance of scheduled follow-up visits (See Follow Up, VIII, page 9 of this protocol).

6. Importance of informing their other providers of their use of COCs.

7. Information regarding discontinuation of COCs, and the recommendation that she complete the cycle of pills she is taking. If she does not wish to get pregnant, she should start using another method before the day she was due to start her next cycle of pills.

8. Information regarding sexually transmitted infections, including counseling that oral contraceptives provide no protection. Use of either male or female condoms should be recommended for clients in need of protection from STDs.

B. All clients choosing to use oral contraceptives must sign the following:

1. General family planning program consent.

2. Hormonal contraceptive consent for the provision of oral contraceptives. (Does not need to be re-initialed yearly unless there is a change in health status).

III. Medical Screening and Evaluation

A. History – as per Title X Guidelines (See Nursing Policy Section IV – Health Care Services)

B. Examination – as per Title X Guidelines (See Nursing Policy Section IV – Health Care Services)

C. Laboratory – tests per Title X Guidelines (See Nursing Policy Section IV – Health Care Services)

D. Provision of oral contraceptives through Delayed Exam – see Delayed Exam protocol

IV. Provision of Oral Contraceptives

CURRENT METHOD	START OCP	BACK UP
No effective contraception in preceding cycle	On or prior to day 5 of cycle, OR take first pill during this office visit if pregnancy can be ruled out (Quick Start), OR take first pill the day after taking emergency contraceptive pills (ECPs) (Jump Start)	Back up method recommended for 7 days
NuvaRing® or Ortho Evra® in preceding cycle	Anytime within 7 days of the last NuvaRing® or Ortho Evra® patch being removed (no later than when a new cycle of NuvaRing® or Ortho Evra® would have been started)	Back up method recommended for 7 days
Progestin-only pills (POPs) in preceding cycle	Any day of the month. There should be no skipped days between last POP pill and first combined OCP	None
Implanon® implant in preceding cycle	On the same day the implant is removed	Back up method recommended for 7 days
DMPA in preceding cycle	On or before the day when the next injection is due	Back up method recommended for 7 days
ParaGard® or Mirena® in place	On the same day that the IUD is removed	Back up method recommended for 7 days
Post first trimester abortion	Within 5 days of a completed procedure	None
Post second trimester abortion and postpartum	3-4 weeks post second trimester abortion; 3-4 weeks postpartum in women who elect not to breast feed, if menses has not restarted; > 6 months postpartum in lactating women.	Back up method should be considered for 7 days

CURRENT METHOD	START OCP	BACK UP
Any other contraceptive method	On first day of cycle On days 2-5 of cycle	No back up method is needed Back up method should be used for 7 days

V. Management of Women With Special Considerations Requiring Further Evaluation

A. Adverse Cardiovascular Risk Profile

B. If a woman has two or more risk factors, the case must be evaluated by, and use of oral contraceptives approved by a physician:

1. Age ≥35;
2. Smoking cigarettes;
3. High cholesterol levels;
4. Diabetes;
5. Chronic hypertension.

C. Diabetes mellitus

1. Oral contraceptive use in women with diabetes must be individualized. As risk factors increase in number or severity, it may become less appropriate to prescribe oral contraceptives
2. Consider involving the primary care provider managing the client's diabetes if she is initiated on oral contraceptives.

D. High Blood Pressure

1. If hypertension is controlled with diet or medication, the complete cardiovascular risk profile (B.1 – 5 above) must be considered.
2. Oral contraceptives may induce hypertension in a very small percentage of previously normotensive women. If a COC user is found to have a significant rise in blood pressure to 140 systolic or above/ 90 diastolic or above, the rise could be due to the use of the COC.
3. Management - **Please refer to the flow chart on the next page for management of hypertension that occurs in women using COCs:**

Flow Chart For the Management of Clients Using Combined Oral Contraceptives (COCs) Who Develop High Blood Pressure

SYSTOLIC 140 or above
And/or
DIASTOLIC 90 or above

↓

Have client return two or more times within two weeks in a resting state for reevaluation.

If any two or more readings on at least two different visits are ≥140 systolic or ≥90 diastolic, consider the following options:

+Physician consultation
+Refer for medical evaluation
+Switch to another method (progestin-only is OK)

Diastolic of ≥100 on any one occasion - stop COCs immediately. **Initiate interim method of contraception;** client must be referred for a medical evaluation.

Continuation of COCs requires documentation of physician approval and a plan for follow-up.

↓

If COCs are discontinued, re-check BP within three months.

- If still ≥140 systolic or ≥ 90 diastolic, refer for evaluation.
- If <140 systolic or <90 diastolic, may then try a very low dose (20 ug estrogen) combination pill or progestin-only method.

If very low dose (20 ug estrogen) combination pill or progestin only method is initiated:

- Monitor BP monthly for three months. If BP rises to ≥140 systolic or ≥90 diastolic at any time, discontinue estrogen-containing hormonal contraceptives.
- Offer alternative method.
- Recheck BP within 3 months. See first bullet in this box.

D. Headaches

1. Management of headaches that start or worsen after the initiation of COCs is up to the discretion of the practitioner and client and may include any of the following:

   a. Referral for headache evaluation;

   b. Change in pill prescription including very low dose COCs (20 ug) or progestin only methods;

   c. Change in birth control method;

   d. For headaches during the hormone free interval, instruct the client to skip the week of placebo pills and immediately start a new pack of COCs (see extended use regimen, VI. C, page 7 of this protocol).

2. Common Migraine Headaches (without focal neurologic symptoms **[visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities]**)

   a. A trial of COCs may be provided for women with a history of migraine headaches <u>without</u> focal neurological symptoms. The client must be advised to report any increase in the frequency and severity of such headaches.

   b. If migraines worsen in frequency or severity, or if focal neurological symptoms or signs **(visual changes, scotoma, flashing lights, dysphasia, numbness of face/extremities)** occur, COCs must be discontinued. Women who develop focal neurological symptoms or signs should be referred promptly for neurologic evaluation.

E. Seizure Disorders

1. A large majority of women with seizure disorders will notice no change in the frequency or severity of seizure activity as a result of initiating oral contraceptives.

2. Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in oral contraceptive users. It is the responsibility of the provider to review a client's anti-seizure medication(s) for potential drug interaction with oral contraceptives.

3. Use of backup barrier methods, and the benefits and risks of using oral contraceptives in women with seizure disorders should be discussed with women who use anti-seizure drugs but who need a high degree of protection. Women who are on certain anti-seizure medications and choose to use oral contraceptives should be advised to use a back up method, such as condoms, for 3 months. Any breakthrough bleeding during this time may indicate a decrease in circulating levels of estrogen and progestin. Such a decrease could result in ovulation. Continued use of a barrier method with oral contraceptives (dual method use) or switching to Depo Provera, Implanon, or an IUD may be advised.

F. Drug Interactions

1. Anti-seizure medications: Concurrent use of anti-seizure drugs that induce hepatic enzymes may reduce effective plasma steroid levels in oral contraceptive users. (See E. above)

2. Gabapentin (Neurontin), vigabatrin, ethosuximide and lamotrigine (Lamictal) have no effect on this enzyme system and do not interfere with contraceptive effectiveness. Valproate/ Valproic Acid (Depakote) and felbamate (Felbatol) do not increase breakdown of hormones and may even increase hormone levels.

3. Rifampin increases hepatic clearance of estrogens and progestins; it is recommended that clinicians not prescribe oral contraceptives for women on this drug (Contraceptive Technology, Eighteenth Edition, p. 436).

4. Antibiotics: Although women on antibiotics do have lower serum progestin and estrogen levels, the levels remain well within the therapeutic range for sex steroids. Back up methods should not be necessary unless the patient has problems taking her pills, e.g., her underlying medical condition interferes with pill taking or absorption, or the antibiotics give her vomiting or diarrhea. (Contraceptive Technology, Eighteenth Edition, p. 437)

5. COCs can decrease clearance of benzodiazepines such as diazepine (Valium), nitrazepine, chlordiazepine, alprazolam, which suggests the need for lower doses of these medications. Clearance of bronchodilators such as theophylline, aminophylline and caffeine as well as anti-inflammatory corticosteroids may also be reduced.

6. More rapid clearance of acetaminophen and aspirin is also reported.

7. The FDA has alerted providers that the use of St. John's Wort may decrease the therapeutic effect of COCs.

VI. Guidelines for Oral Contraceptive Use and Management of Problems/Side Effects

A. Missed Oral Contraceptive Pills/ Consideration of Emergency Contraception

Current research supports the belief that the greatest risk of pregnancy results from missing pills on either side of the week of spacer pills (COCs), thus extending the pill-free interval beyond 7 days. Therefore, pills missed mid-cycle are much less likely to result in pregnancy than pills missed just before or after the week of spacer pills. There is no pill free interval with progestin only pills (POPs); late or missing pills anytime in the cycle may pose a risk of pregnancy.

1. Women that are late taking a pill

   a. Take the missed pill ASAP and take the next pill at the usual time.

   b. No back-up method of birth control is necessary unless this one pill extends the pill-free interval.

2. Women that have missed 1 pill (>24 hours has elapsed since the last pill was taken).

   a. Take both the missed pill and today's pill at the same time;

   b. A back-up method of birth control should be used for 7 days after the pills are missed.

3. Women that have missed 2 pills (1 pill has been missed and the woman is late or has completely missed the second pill)

   a. Take the last pill that was missed ASAP.

b. Take the next pill on time.

c. Throw out the other missed pills.

d. Take the rest of the pills in the package right on schedule.

e. A back-up method of contraception should be used for 7 days after the pills are missed.

4. Women that miss pills during the third week of pills (pills 15-21 or during the week before the spacer pills). (This is not relevant for progesterone only pill [POP] users.)

a. Finish the rest of the hormonal pills in the pack.

b. Do NOT take the spacer pills.

c. Start taking a new pack of pills as soon as the current pack is finished. Clients may not have a period until the end of the second pack of pills.

d. A back-up method of birth control should be used for 7 days.

5. When to consider emergency contraception (ECP) in a woman that has missed oral contraceptives.

a. Contraceptive Technology, (Eighteenth Edition, p. 288) recommends that ECP be considered when a woman misses too many pills at the wrong time:

- 2 or more days late starting a new pill pack
- 2 or more combined OC pills during the first week of a pill pack
- 5 or more pills during the second or third week of a pill pack

b. Contraceptive Technology, (Eighteenth Edition, p. 291) advises it is reasonable to offer ECP no matter how many pills have been missed if the woman is worried or wants to avoid even the smallest risk of pregnancy.

B. Extended Use or Continuous Cycling: Consider offering clients the opportunity of fewer withdrawal bleeds during the year by skipping the placebo pills for up to 4 packs in a row, particularly if they experience estrogen withdrawal symptoms such as headache when taking the placebo pills during the fourth week of the pill pack. The prescription needs to be written for 16-17 cycles/year. As an alternative to the more expensive products with dedicated packaging for extended use, select a monophasic pill for extended use or continuous cycling. Please refer to, Contraceptive Technology, Eighteenth Revised Edition, p. 422: "Options for extended use include the following…"

C. Changing COCs and back-up methods.

1. There is no need for a back-up method when switching between brands unless pills have been missed or a client is being switched from a 50mcg pill to a lower dose COC or a POP. If pills have been missed, follow the directions above.

2. When switching, the client can be started on the new pill on the first day of the pill free interval.

VII. Progestin-only Pills (Mini-pills or POPs)

A pregnancy that does occur in a woman taking mini-pills is more likely to be ectopic. Some sources postulate that 10% of pregnancies that occur to mini-pill users are ectopic (Contraceptive Technology, Eighteenth Edition, p. 466).

A. Precautions

1. Refrain from providing progestin-only pills (POPs) for women with the following diagnoses:

   a. Suspected pregnancy;

   b. Breast cancer.

2. Exercise caution if POPs are used in the following situations and carefully monitor for adverse effects.

   a. Certain anti-seizure medications or use of rifampin cause the liver to metabolize progestins more rapidly.

   b. Breast cancer with a 5-year disease-free interval - some breast cancers are sensitive to progestins.

   c. Liver conditions such as severe decompensated cirrhosis, adenoma or cancer, active viral hepatitis.

   d. Current deep vein thrombosis

3. Initiating progestin-only pills

   a. Follow instructions for initiating combined oral contraceptives (COCs).

   b. Progestin-only pills (POPs) may be started in non-lactating women at any time postpartum and at six weeks postpartum for lactating women. It is probably acceptable to start a breast-feeding woman on POPs before six weeks postpartum if she desires, as long as breastfeeding has been established. (Read the pros and cons in, Contraceptive Technology, Eighteenth Edition, Chapter 23: Postpartum Contraception and Lactation, pp. 582-590)

VIII. Follow Up

A. The new oral contraceptive user must be reassessed within three months after beginning the pill, and at least annually thereafter.

B. Please refer to Section V (Health Care Services) in the Nursing Policy Manual for a complete review of the requirements for revisits for OCP users.

C. At each oral contraceptive related medical visit (not to include routine supply visits), the client should be asked about changes in personal history, possible side effects, and her menstrual cycle/bleeding pattern.

The following is a sample of a Hormonal Consent Form. This form can be downloaded from the Women's Health Unit website at:
http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

HORMONAL CONSENT

- **ORAL CONTRACEPTIVE (Combined and POP) • ORTHO EVRA • NUVARING**

I have been given information about and have had a chance to ask questions about:

☐ ?Birth control pills: ☐ Combined ☐ Progesterone Only ☐ ?Ortho Evra patch ☐ ?NuvaRing

I know that:

- Birth control pills and Ortho Evra patch do not require a back up method if I start on the first day of my period.
- Progesterone only pills (POP) only have the hormone progesterone. This may make the effectiveness slightly lower than combined birth control pills. I know that I need to take a pill **every day without a break**. There is no hormone-free week like there is with combined pills. My periods might be irregular.
- NuvaRing is left in the vagina for three weeks from the day I insert it, and is then removed and thrown away. A new ring is inserted one week (7 days) after removal of the old one.
- **Ortho Evra (the patch) results in a 60% increase in exposure to estrogen compared to the average birth control pill. It is not known whether this results in a significant increased risk of blood clots.**
- The hormonal methods listed above do not provide me with protection from sexually transmitted diseases. If I need this protection, I have been advised to use condoms PLUS this method.

I have been told that there may be some medical risks when using any of the combined hormonal methods that could include such things as stroke, blood clots, or liver tumors. I have been given a copy of the "Detailed Patient Labeling" which tells how often these problems happen.

I understand that the cardiovascular risks of this method may get worse with age, especially over 35 years of age, and with smoking. I know that the serious health problems that this method can cause are rare. I know to call the clinic or my private doctor, or to go to the emergency room if I have any of these danger signs:

- Severe abdominal pain;
- Chest pain;
- Severe headaches;
- Changes in my vision;
- Severe leg pain.

If I wish to discontinue my method, I have been advised that it is better for me to finish the cycle I am taking before stopping the method. If I do not wish to become pregnant, I must start on another method immediately.

Patient signature **Date**

Staff signature **Date**

Interpreter's Statement

I have translated the information and advice presented orally to the client who has chosen:

☐ Combined birth control pills ☐ Progesterone only birth control pills
☐ Ortho Evra Patch ☐ NuvaRing

I have also read the consent form to her in a language she understands and explained its contents to her. To the best of my knowledge and belief, she understands this explanation and voluntarily consents to the use of the method marked above.

Interpreter's signature **Date**

The following is a sample of a Hormonal Evaluation Form. This form can be downloaded from the Women's Health Unit website at:
http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

HORMONAL METHOD EVALUATION
ORAL CONTRACEPTIVES (Combined and POP),
EVRA PATCH, NUVARING, IMPLANON (rod implant)

Name _____ **Today's date** _____

Date of birth _____ **Age** _____

First day of last period _____

1. **Please check your current method:**

   ☐ Birth control pill (Combined)
   ☐ Evra
   ☐ Implanon
   ☐ Birth control pill (Progesterone only)
   ☐ Nuvaring

2. **Are you having any problems with your method?** ☐ **No** ☐ **Yes**
   Explain: _____

3. **Do you have any questions?** ☐ **No** ☐ **Yes**
   Explain: _____

4. **Have you had any health problems or seen a physician since your last visit?**
   ☐ **No** ☐ **Yes Explain:** _____

5. **Are you taking any other medications?** ☐ **No** ☐ **Yes**
   List: _____

6. **Check if you have had any of the following since you started your method:**

   ☐ Severe headaches
   ☐ Dizziness
   ☐ Vision changes
   ☐ Chest pain
   ☐ Severe leg pain
   ☐ Severe abdominal pain
   ☐ Depression
   ☐ Nausea or vomiting
   ☐ Heavy bleeding
   ☐ Weight gain

_____
Client Signature **Date**

TO BE COMPLETED BY STAFF

S:

O: B/P____ **WT**____

A:

P:

_____
Staff signature **Date**

The following is a sample of a Headache Evaluation Form. This form can be downloaded from the Women's Health Unit website at:
http://www.cdphe.state.co.us/pp/womens/FPNursingConsntsForms.html.

Headache Evaluation Form

Client #_____ Name _____ Age_____

When you have headaches, how often do you…… (Circle one answer per question)

1. Feel them coming on before they become headaches?	Never	Rarely	Usually	Always
2. Have moderate to severe pain?	Never	Rarely	Usually	Always
3. Have pulsating, pounding, or throbbing pain?	Never	Rarely	Usually	Always
4. Have worse pain on one side of your head?	Never	Rarely	Usually	Always
5. Have worse pain when you move, bend over or walk stairs?	Never	Rarely	Usually	Always
6. Have nausea?	Never	Rarely	Usually	Always
7. Have vomiting?	Never	Rarely	Usually	Always
8. Feel bothered by light?	Never	Rarely	Usually	Always
9. Feel bothered by sound?	Never	Rarely	Usually	Always
10. Need to limit or avoid daily activities?	Never	Rarely	Usually	Always
11. Want to lie down in a quiet, dark room?	Never	Rarely	Usually	Always
12. See zigzag lines, spots, or light flashes?	Never	Rarely	Usually	Always

To give your healthcare provider more complete information, please answer these additional questions:

1. Do any immediate family members also suffer from headaches? Yes No
2. In your lifetime, have you had at least 5 headaches with the symptoms noted above? Yes No
3. At what age did you first experience these headaches?_____
4. On average, how often do you get these headaches? _____
5. Which medicine(s) do you take for your headaches? _____

Check all of the statements that are true:

1. My headache medicine does not make me pain free. ____
2. My headache medicine does not treat other symptoms (e.g., nausea, sensitivity to light). ____
3. I take my headache medicine more than 2 or 3 times per week. ____
4. My headache medicine makes me drowsy. ____
5. I take more than one kind of medicine for my headaches. ____
6. My headache may last 4 to 72 hours (untreated or unsuccessfully treated). ____

Check any of the following that ever bring on one of these headaches:

___Intense lights, smells, or sounds
___Weather changes
___Allergies or sinus pain/pressure
___Stress or tension
___Monthly menstrual cycle/hormonal changes
____Too little sleep or too much sleep
____Missed meals
____Lack of caffeine or too much caffeine
____Changes in mood/excitement
____Foods or alcoholic beverages

Client's Signature:_____Date:_____

TO BE COMPLETED BY STAFF
Assessment:

_____
Clinician Signature Date Agency Name