I. Subjective Data

A. Refrain from providing in the following conditions (Based on WHO Medical Eligibility Criteria and FDA package insert)

1. Pregnancy or suspicion of pregnancy.
2. Distorted uterine cavity.
3. Acute PID or a current history suggesting a high risk for PID.
4. Hx. PID without intervening intrauterine pregnancy – Mirena only
5. Postpartum or postabortal endometritis in the past 3 months.
6. Known or suspected uterine or cervical malignancy.
7. Genital bleeding of unknown source.
8. Mucopurulent cervicitis.
9. Wilson's disease (ParaGard).
10. Allergy to copper (ParaGard).
11. Previously placed intrauterine contraceptive that has not been removed.
12. Known breast cancer (Mirena)
13. Acute liver disease or liver tumor (Mirena)

B. Exercise caution in the following situations. Clients must be provided with information regarding additional health risks to her and this must be documented. (Based on WHO Medical Eligibility Criteria and FDA package insert)

1. Risk factors for STD or HIV/AIDS, including multiple sexual partners or a partner who has multiple sexual partners. This is a contraindication for Mirena – don't provide
2. Women who are immunocompromised.
3. Previous problem with IUD/IUS (document nature of problem).
4. Past history of severe vasovagal reactivity or fainting.
5. Difficulty obtaining emergency follow-up care and treatment for PID.
6. Uterine cavity sounding <6 cm.

C. Advantages generally outweigh theoretical or proven disadvantages; generally can be provided without restriction in these conditions. (Based on WHO Medical Eligibility Criteria)

1. Valvular heart disease such as aortic stenosis without complications.

2. Uterine fibroids, very narrow cervical canal, cervical lacerations, or other anatomical abnormality that does not distort the uterus.

3. Heavy or prolonged menstrual bleeding without clinical signs of anemia.

II. Objective Data

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

B. Laboratory tests to include (but not be limited to):

1. Pap smear which rules out cervical malignancy within the normal screening interval for the client. Abnormal Pap smear ≤LSIL receiving appropriate management and follow up is not a contraindication to insertion of an IUD.

2. GC and Chlamydia tests within 60 days; may be done at the time of insertion.

III. Assessment and Plan

A. Client Education/ Informed Consent

1. Have patient read the FDA approved patient brochure for the particular IUD/IUS that she is to have inserted.

2. Reinforce the effects of the IUD/IUS on the menstrual cycle.

3. Client must sign the client consent, supplied by this office. The white (top) copy of the NCR consent from this office must be kept with the chart and the yellow copy of the consent and the patient package insert included with the IUD/IUS must be given to the client. The consent must be signed the same day as the insertion.

B. Preinsertion Management

1. The latest U.S. trial (Walsh, et.al., 1998) suggests that the use of prophylactic antibiotics at the time of IUD/IUS insertion is not beneficial.

2. Sub-bacterial endocarditis (SBE) prophylaxis prior to IUD/IUS insertion is not recommended (American Heart Association, JAMA 264: 2919, 1990: AMA Drug Evaluation 4:1, 1994).

3. For preinsertion pain management, patients may be given a non-steroidal anti-inflammatory drug (NSAID), such as Ibuprofen 400 mg ii tabs p.o. 30 - 60 minutes prior to insertion or a paracervical block may be used.

4. If the client has a stenotic os, consider administration of Misoprostol **400** ug intravaginally 2-4 hours before insertion of IUD/IUS. (Contraceptive Technology, 19th Revised Edition, pg. 128)

C. IUD/IUS Insertion

1. No scientific reasoning supports the common practice of only inserting an IUD/IUS during menses (Contraceptive Technology, Eighteenth Edition, p. 505). Insert an IUD/IUS at any time during the menstrual cycle under any the following conditions as long as pregnancy can be ruled out:

   a. No unprotected intercourse since LMP;

   b. On a highly effective hormonal method of birth control and thus reasonably sure she is not pregnant;

   c. Postpartum insertion

      (1) Non-breastfeeding women – IUD/IUS may be inserted at ≥4 weeks postpartum if the client has not had menses, has not had intercourse since delivery or has used a reliable method of contraception with each act of intercourse.

      (2) Breastfeeding women – insertion at ≥6 weeks postpartum is preferable. Although a few case reports and a small study suggested a higher risk of perforation among breastfeeding women, other studies find no evidence of increased risk in breastfeeding women and low rate of perforation in both breastfeeding and non-breastfeeding women.

   d. Immediately after or within 3 weeks following abortion with a well-involuted uterus and no post-abortion sepsis.

   e. Within 7 days of unprotected intercourse and desires emergency contraception with an IUD (copper-bearing only).

2. Document baseline pulse and blood pressure prior to insertion.

3. Document IUD/IUS type, depth to which uterus is sounded, string length after insertion and trimming, and lot # of the IUD/IUS.

D. Postinsertion of the IUD/IUS - Vasovagal observation

1. Blood pressure and pulse should be taken and recorded.

2. If VS indicate a vasovagal response, record BP and pulse frequently (every 5-15 minutes).

3. Client should not be allowed to leave the clinic until stable.

4. Clients with persistent vasovagal symptoms should be evaluated for perforation, abdominal bleeding, etc.

E. Post-IUD/IUS Insertion Education

1. Client should be instructed on the expiration period for the IUD/IUS.

   a. ParaGard is approved for 10 years.

   b. Mirena is approved for 5 years.

2. Reinforce the signs and symptoms of possible IUD/IUS complications. Instruct the client to call the clinic for any of the following:

   a. Late or missed period; abnormal spotting or bleeding (ParaGard only); signs or symptoms of pregnancy.

   b. Pelvic or lower abdominal pain; pain with intercourse

   c. Exposure to STDs; abnormal vaginal discharge

   d. Not feeling well – fever or chills

   e. Inability to locate IUD/IUS string, changes in string length

   f. Known expulsion

3. Instruct the client to check for the string before intercourse, during her first menstrual cycle, and then after each menses.

4. Inform the client if she wishes to discontinue the use of her IUD/IUS, she needs to make an appointment with her provider to have it removed. If she does not wish to become pregnant, she must start a new method on or before the day she has her IUD/IUS removed.

F. Follow-up Visits

The 2-3 month post-IUD/IUS exam (4 weeks after next menses optimal) is to include:

1. Completed IUD/IUS Evaluation Form

2. Hemoglobin/ Hematocrit if indicated

3. Complete pelvic exam (performed and documented)

4. Documentation of visualization of string and its length

5. Review of IUD/IUS danger signs.

6. Reinforce the importance of an annual physical exam and Pap smear as per screening guidelines.

IV. Management of Complications/Side Effects

A. Patient Diagnosed with PID

1. Treat for PID as outlined in the STD protocol. There is no evidence supporting the requirement that the IUD/IUS should be removed with acute PID. (Contraceptive Technology, 18th Revised Edition, p. 526 and Sexually Transmitted Diseases: Treatment Guidelines, 2006, Centers for Disease Control and Prevention, p. 61) However, if the IUD is not removed, close clinical follow up is mandatory. Note that the Mirena package insert recommends removal after initiation of antibiotics. In making this decision, the local agency must consider the possibility that the client won't return for removal of the IUD/IUS after antimicrobial therapy begins.

2. Inform the client to seek care immediately if her symptoms worsen, as outlined in the STD protocol.

3. If the IUD/IUS is removed, contraceptive counseling is necessary.

   a. If the patient is mid-cycle, and has recently had intercourse, inform her of the risk of removing the IUD/IUS and a possible subsequent pregnancy. Offer ECP. If the patient decides she does not want removal, documentation must exist of discussion of need for close clinical follow up.

   b. If IUD/IUS is removed, be certain the patient leaves the clinic with an alternative method of birth control.

4. Actinomyces on Pap smear - **SYMPTOMATIC OF PID**

   a. Client must receive/ be referred for intensive antibiotic therapy, along with the removal of the IUD/IUS, as this bacterium prefers to grow on foreign bodies. Physician consultation is required.

   b. Patient must be counseled on the use of a different method of contraception.

B. Actinomyces on Pap smear **- ASYMPTOMATIC OF PID**

Pelvic actinomycosis is a rare (<.001%) but serious condition. The relationship between actinomyces found on a Pap smear in the asymptomatic IUD user and development of a pelvic actinomycosis infection is not clear. Therefore, management of the asymptomatic IUD user with a Pap with actinomyces is not clearly established. There has only been one small, randomized controlled trial, and the results established no superior approach. "The options for management of asymptomatic IUD users with actinomyces on Pap test are expectant management, an extended course of oral antibiotics, removal of the IUD, and both antibiotic use and IUD removal." ACOG Practice Bulletin No. 59, January 2005. With this is mind, each agency's practitioners should discuss the management of actinomyces on Pap smear in an asymptomatic IUD user with the medical consultant and determine the approach to be used.

1. Review the result with the cytologist/pathologist to confirm the diagnosis.

2. The IUD/IUS does not have to be removed, but the client should be informed and questioned about any symptoms suggestive of PID. If she is asymptomatic, nothing more is required.

3. See the paragraph above Number 1 regarding treatment. Treatment with antibiotics is an option. If antibiotics are used, treat with Ampicillin 250 mg qid x 14 days. Review the signs and symptoms of PID with the client.

4. Since the importance of clearing the actinomyces colonization in the asymptomatic client is not established, there is no basis for recommending a repeat Pap to check for clearing of actinomyces.

C. Spotting, Bleeding

1. Rule out pregnancy, infection or partial expulsion and manage appropriately.

2. If client complains of excess bleeding within the first three months after insertion,

   a. Reassure that it is likely to get better in subsequent cycles,

b. Check hct or hgb and give ferrous supplement, if indicated,

c. Ibuprofen 600 qid for first three days of cycle,

d. Rule out other pathology related to vaginal bleeding.

D. Cramping or Pain – varying degrees of discomfort may be felt at the time of insertion and may be followed by cramping pain over the next 10-15 minutes.

1. Pain with sounding of the uterus during insertion

a. Go slowly, consider smaller sound

b. If severe, check alignment of uterine cavity on bimanual exam, and consider using a paracervical block before proceeding.

2. Cramping or pain immediately post-insertion, for a few days after or with each menses

a. If severe: rule out perforation, pregnancy or infection. Check BP & pulse. Consider removing the IUD/IUS if indicated.

b. If mild: prescribe a mild analgesic such as Ibuprofen 600 mg po every 6 hours prn.

3. Severe post-insertion reaction, such as syncope

a. If placement is questionable, remove the IUD/IUS. An IUD/IUS can be re-inserted now or at a later date.

b. If the IUD/IUS is properly placed, and pulse <60 beats/min, consider atropine 0.4-0.6 mg IM or IV and consider an analgesic such as ibuprofen or acetominophen.

c. Remove the IUD/IUS if necessary.

4. Pain at the time of insertion persists, with signs of abdominal tenderness

a. If the string is present, treat as pelvic infection

b. If the string is absent, consider possibility of perforation, migration, expulsion or pregnancy and refer to physician.

5. Partial expulsion of IUD/IUS

a. Without signs of infection, remove IUD/IUS and another IUD/IUS may be inserted.

b. With PID or question of PID, treat with antibiotics and remove the partially expelled IUD/IUS. Provide alternative contraception. Another IUD/IUS may be inserted after 3 cycles.

E. Pregnancy with IUD/IUS in situ - A woman pregnant with an IUD/IUS in place must be evaluated promptly to confirm an intrauterine pregnancy and to exclude an ectopic pregnancy.

1. Do highly sensitive pregnancy test. Pelvic exam, if indicated.

2. If the client is pregnant and the IUD/IUS string is visible, the IUD/IUS should be removed, regardless of plans to continue or terminate the pregnancy.

   a. Counsel the client that an ectopic pregnancy, SAB, or sepsis is a possibility and review signs and symptoms of each.

   b. Refer the client for health care services.

3. If the client is pregnant and the string not visible, explain the risks of ectopic pregnancy, SAB and sepsis with an IUD/IUS in situ during pregnancy.

   a. Review the warning signs of infection, SAB and ectopic pregnancy, including where to seek emergency care.

   b. Refer to physician immediately for follow-up.

4. Ectopic pregnancy

   IUD/IUS significantly reduces a woman's risk of an ectopic pregnancy, because the IUD/IUS prevents all types of pregnancies. Should a pregnancy occur with an IUD/IUS in place, the ratio of ectopic to intrauterine pregnancies may be increased. (Contraceptive Technology, Eighteenth Edition, p. 505)

F. Absent IUD Strings

1. If menses have not been missed and there is no abdominal pain:

   a. After ruling out pregnancy (as indicated), attempt to determine if the IUD/IUS is in the uterus by gently exploring the cervix for the strings.

   b. If the strings are located, bring them to their appropriate place.

   c. If the strings are not found, the clinician may elect to discuss an alternative method of contraception with the client and have her return with the next menses to check again for the string OR obtain a pelvic ultrasound to determine if the IUD/IUS is in the uterus.

      (1) If the IUD/IUS is seen on ultrasound, clarify the location to R/O perforation. If the IUD/IUS is in the uterus, nothing else needs to be done.

      (2) If the IUD/IUS is not located by pelvic ultrasound, order an abdominal X-ray to differentiate IUD/IUS expulsion from translocation into the abdominal cavity. Translocated intraperitoneal IUD/IUS should be removed as promptly as possible, as copper-bearing IUDs are known to cause dense adhesions.

2. If menses have been missed and/or there are s/sx of infection:

   a. Rule out pregnancy

   b. See management of pregnancy with IUD/IUS in situ or PID with IUD/IUS.

V. IUD/IUS Removal

A. Subjective Data

1. LMP and previous menstrual period
2. Medical history update
3. History of recent intercourse, if patient not menstruating
4. Reason for IUD/IUS removal

B. Objective Data

1. Physical exam/pelvic exam as indicated.
2. Laboratory as indicated.

C. Assessment and Plan

1. Client requesting reinsertion of IUD/IUS:

   Reinsertion may be done at the same visit, at the discretion of the provider

2. Client requesting change in contraceptive method

   a. Counsel regarding other methods of birth control. Hormonal methods may be initiated before the IUD/IUS is removed.

   b. Remove IUD/IUS (if client is not menstruating, counsel on risks of pregnancy)

   c. Provide interim method of birth control, as indicated.

   d. If pregnancy is desired, preconception counseling, including the benefits of folic acid, should be done.

3. Client symptomatic of PID – refer to IV.A on page 4 of this protocol.

The following is a sample of an Intrauterine Device/System 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.

INTRAUTERINE DEVICE/SYSTEM CONSENT

I got the information and asked all my questions about:

☐ ?ParaGard Intrauterine Device (IUD) ☐ ?Mirena Intrauterine System (IUS)

I know that:

- The IUD/IUS prevents pregnancy more than 99% of the time. It provides long term protection from pregnancy
  - Each ParaGard IUD is good for 10 years of use. Each Mirena IUS is good for 5 years of use.
- Mirena IUS contains the hormone progestin and may decrease menstrual bleeding and cramps.
  - The IUD/IUS does not protect me from sexually transmitted infections. If I need this protection, I will use condoms PLUS this method.

I know the IUD/IUS might cause the following:

- Spotting, irregular bleeding, heavier periods;
- Cramping when it is put in at the clinic and during my periods;
- Making a hole in the wall of the uterus when it is put in at the clinic;
- String may not be found at future visits, or other string problems.

I have a copy of the "Information for Patients" which gives more details about these and other risks/side effects. My health care provider has told me the following reasons why a person should not use the IUD/IUS:

- Current Pelvic Infection (PID) or high risk for sexually transmitted infections;
- Current pregnancy or suspicion of current pregnancy;
- Known or suspected uterine/cervical cancer; or breast cancer (for Mirena);
- Wilson's disease;
- Allergy to copper (for ParaGard);
- Uneven shape of the uterus.

I will call the clinic or my private doctor, or go to the emergency room if I have any of these danger signs:

- Late or missed period; abnormal spotting or bleeding; signs or symptoms or pregnancy;
- Pelvic or lower abdominal pain; pain with intercourse;
- Exposure to sexually transmitted infections; abnormal vaginal discharge;
- Fever or chills;
- Cannot locate the string;
- The IUD/IUS has come part of the way out, or all the way out, of the uterus.

If I have problems or concerns, I will come back to the clinic to talk with a nurse or doctor to see if I can make the IUD/IUS work for me. If I wish to stop using the IUD/IUS, I know that I need to come back to the clinic to have it taken out. If I do not wish to become pregnant, I must start on another method right away.

_____ _____
Patient signature **Date**

_____ _____
Staff signature **Agency** **Date**

Interpreter's Statement

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

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 IUD/IUS.

_____ _____
Interpreter's signature **Date**

The following is a sample of an IUD/IUS 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.

IUD/IUS EVALUATION FORM

Name _____ **Agency** _____

Date of birth _____ **Type of IUD/IUS** _____

Insertion Date: _____

1. When must your IUD/IUS be removed: _____ Month/Year
2. First day of last menstrual period? _____
3. Can you feel your IUD/IUS string? ? ?No ? ?Yes
4. Are you satisfied with your IUD/IUS? ? ?No ? ?Yes
5. Is your partner satisfied with your IUD/IUS? ? ?No ? ?Yes
6. Since your IUD/IUS was inserted, have you had any infections or sexually transmitted disease?

   ? ?No ? ?Yes ? ?Don't know

7. Check if you have any of the following:

? Cramping
? Burning with urination
? Back pain
? Unusual vaginal discharge
? Heavy bleeding with periods
? Fever
? Pain with intercourse
? Bleeding between periods

8. How often should you check for your IUD/IUS strings?
   a. Frequently
   b. After each period
   c. Anytime you have abnormal bleeding or cramping
   d. All of the above
9. You may not be protected if:
   a. You cannot feel the string
   b. You can feel the plastic
   c. The string gets longer or shorter
   d. All of the above
10. Your IUD/IUS should be removed or changed (circle all that apply):
   a. Once you reach menopause
   b. 3 months before you want a pregnancy
   c. 5 years after insertion
   d. 10 years after insertion
   e. Whenever I wish to change methods
   f. f. None of the above

Do you have any questions about the IUD/IUS? ? ?No ? ?Yes

Patient signature **Date**

TO BE COMPLETED BY STAFF

S:

O:

Examination	WNL	Abn.	Comments
Ext. Genitalia			
Vagina			
Cervix			String visualized: ? yes ? no
Discharge			
Uterus			
Adnexae			

A:

P:

Staff signature **Date**

CDPHE/WHS Reviewed 7.08