Guidance on Protocol Development

Title X Guidelines indicate the requirement of Title X funded agencies having policies, procedures and protocols.

**Policies are:**
- Statements that reflect agency intent and may be based on state or federal law/regulations. They identify type and limits of services and provide general decision making direction.
- Indicated in the Title X “Program Guidelines” about Voluntary Participation (Section 5.1); Confidentiality (Section 5.2) and Fee Collection (Section 6.3). In addition, OPA “Program Instructions” also may indicate policy development such as, documentation of a National Standard of Care for services provided (OPA 09-01); and compliance with state reporting laws (OPA 06-01).

**Procedures are:**
- Descriptions of the specific steps to be taken to complete a specific task/action. They describe how to implement policies.
- Indicated in Title X “Program Guidelines” about service plans (7.1); referrals and follow-up (Section 7.4) and laboratory services (8.3).

**Protocols are:**
- In a clinical setting, a pre-established diagnostic pathway. They are an outline of when and what action will be taken. They are a decision making tree for clinical services and are essential for assuring practice within scope of license.
- According to Title X “Program Guidelines” protocols are indicated for all services provided (Section 7.1); and medical emergencies (Section 7.3). According to OPA Program Instructions, 09-01, “Clinical protocols should reflect the current recommendations for practice or standards of care established by health agencies or professionals”. In addition, “Title X grantees are responsible for ensuring that all sub-recipient agencies maintain and use written clinical protocols that are consistent with nationally recognized practice standards”.

In an effort to provide assistance in the local agency development of protocols that are consistent with current National Standards of care, the Office of Population Affairs has suggested several acceptable resources:

- Centers for Disease Control and Prevention (CDC): [http://www.cdc.gov](http://www.cdc.gov)
- American College of Obstetricians and Gynecologists (ACOG): [http://www.acog.org](http://www.acog.org)
Partners in Information Access for Public Health Resources (Department of Health and Human Services):
http://phpartners.org/guide.html
National Heart Lung and Blood Institute (NHLBI) (Department of Health and Human Services):
http://www.nhlbi.nih.gov/health/indexpro.htm

The Oregon Reproductive Health Program staff is available to assist in protocol development, share sample protocols and send information about new/updated “National Standards” as they become available to all agency Reproductive Health Coordinators. As each Title X agency develops or revises its own policy/procedures/protocols, it is required that they identify and document the National Standard of Care being used.