1. **PURPOSE**

The purpose of this document is to define the policies and procedures for providing services to patients in the Prenatal Immunology Clinic.

1. **DEFINITIONS & ABBREVIATIONS**

PRIM = Prenatal Immunology Clinic

QCM = Quality Control Management

HIV = Human Immunodeficiency Virus

HLS = HIV Linkage Specialist

PCP = Primary Care Provider

TOPWA = Targeted Outreach for Pregnant Women Act

FDOH = Florida Department of Health

ARNP = Advanced Registered Nurse Practitioner

RN = Registered Nurse

JHS = Jackson Health System

ACC= Ambulatory Care Center

OB= Obstetrics

US= Ultrasound

STIs = Sexually Transmitted Infections

ACOG = American College of Obstetricians and Gynecology

CDC = Centers for Disease Control

ASCCP = American Society for Colposcopy and Cervical Pathology

ATU = Antenatal Testing Unit

LD = Labor and Delivery

PP = Post-partum

SI = Special Immunology

Cerner = the JHS Electronic Medical Record system

Careware = OB/Gyn SI Data base - CW

1. **RESPONSIBILITY** 
   1. The Medical Director of the Clinic has the final authority on policies and procedures involving the operation of the PRIM Clinic.
2. **PROCEDURE**

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| **Requesting an Initial Appointment** | MD | NP | RN | ES | HLS | MA |
| Patient, referring doctor, etc…calls 305-243-5832 (main line) or 243-5645 to make an appointment. HIV Linkage Specialist (HLS) answers the line. If she is unavailable, the phone number is transferred to the Quality Control Management (QCM) Director (305-243-2170). |  |  |  |  | X |  |
| HLS starts a file on the patient before they are seen. She requires proof of pregnancy, proof of HIV status, recent results (if any), referral (if needed by referring doctor or PCP) and prior authorization if required, copy of ID, name and info on insurance carrier. |  |  |  |  | X |  |
| HLS requests a referral be faxed from the referring physician. Once received, HLS schedules appoint in Cerner within 7 days. All the documents are scanned into CAREWare. |  |  |  |  | X |  |
| If HLS is unfamiliar with the insurance carrier, she will call the carrier after she makes an appointment to confirm coverage. If the patient has Medicaid, they are run through the Medicaid system. If the patient has private insurance, HLS will call the carrier to see if a prior authorization is needed. She enters the authorization number in Cerner. |  |  |  |  | X |  |
| HLS asks the patient if transportation is needed. If so, they are given the TOPWA phone number and fills out a TOPWA referral for them to pick up the patient. |  |  |  |  | X |  |
| HLS contacts the Perinatal HIV Coordinator in FDOH after every new patient is scheduled to report a new case. |  |  |  |  | X |  |

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| **Pre-Clinic Meetings and Activities** | MD | NP | RN | ES | HLS | MA |
| Fridays: ARNPs receive a hard copy of next week’s schedule for all clinics. |  | X |  |  |  |  |
| Mondays at 3pm: ARNPs, Part D Director, Part C QCM Director, Medical Case Manager (Sr. HIM Technician), RN, Medical Assistant, and Eligibility Specialist meet to go over the week’s schedule and address any issues. |  | X | X | X | X | X |
| PRIM Pre-Clinic Meeting; Tuesdays at 2:30pm: ARNPs, RNs, Eligibility Specialist, Mental Health Specialist, and Pediatrics meet with the PRIM Medical Director to go over every OB patient scheduled for the week. |  | X | X | X |  |  |
| RN calls the patient 2 days prior to the appointment as a reminder. PRIM Clinics are held on Thursdays from 8:30am – 5pm in ACC West 4B. The first appointment is always in the morning. Obstetric ultrasound and / or lab work can be scheduled for the same day if needed. |  |  | X |  |  |  |
|  | MD | NP | RN | ES | HLS | MA |
| If the patient misses the initial appointment, a note is entered into CAREWare, and the patient is automatically rescheduled. HLS calls patients to discuss why they missed the visit and informs them of the new visit. |  |  |  |  | X |  |
| If the patient misses the follow-up appointment, RN will call and bill for the call. |  |  | X |  |  |  |
| After 3 no shows (or before if the patient is in the third trimester), the patient is reported to FDOH. |  |  |  |  | X |  |

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| **Consent** | MD | NP | RN | ES | HLS | MA |
| Patient has to sign consent for treatment and consent for outreach if they fall out of treatment. Consents are kept in the chart and scanned into Cerner. |  |  |  | X |  |  |
| Orient the patient to the clinic service. |  | X |  |  |  |  |
| Ensure the patient is enrolled in free or low-cost social service programs for which she is eligible (eg. WIC, food stamps, Medicaid, Ryan White, ADAP, etc) |  | X |  |  |  |  |

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| **Patient Assessment and Management** | MD | NP | RN | ES | HLS | MA |
| During the first visit, the ARNP takes a comprehensive health history, performs a complete head to toe physical exam, orders or reviews labs and diagnostic tests, makes assessment, estimates EDC, explores patient’s feelings toward pregnancy and discuss options, evaluates maternal and fetal well- being, identifies risk factors, develops a plan of care including pharmacologic and non-pharmacologic measures, patient education, follow-up, consults and referrals as needed (ie. Nutritionist).  Comprehensive health history includes but is not limited to: medical, obstetrical, genetic, gynecologic, contraceptive, nutritional, lifestyles, surgical, family, social including screening for substance use, domestic violence and human trafficking. HIV related history: past and current use of antiretroviral medications, resistance testing, mutations, compliance, hospitalizations or diseases related to the HIV infection, and co-morbidities.  Complete physical exam includes but is not limited to general exam, obstetric and pelvic exam (fundal height, fetal heart tones, cervical pap smear, STIs screening, drug use screening, presence or absence of HIV related pathology). |  | X |  |  |  |  |

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| **Labs and Diagnostic Tests** | MD | NP | RN | ES | HLS | MA |
| If the patient comes in without a confirmed HIV diagnosis, appropriate HIV tests are ordered to confirm diagnosis. |  | X |  |  |  |  |
| Initial prenatal labs are requested or reviewed and include but are not limited to: CBC, CMP, syphilis IgG, ABO, antibody screen, rubella IgG, Hepatitis B surface antigen, Hepatitis C Virus antibody, sickle cell screening, urinalysis, urine culture, antenatal maternal testing, T-cells, HIV viral load, HIV genotype, HLA-B\*5701, Quantiferon TB, Drug Abuse screening in urine, and other pertinent lab tests depending on each case. |  | X |  |  |  |  |
| OB U/S or other diagnostic testing as per protocol or as needed |  | X |  |  |  |  |
| **Assessment** | MD | NP | RN | ES | HLS | MA |
| The patient assessment is completed in the JHS Prenatal History & Physical form that is part of the patient’s medical chart. |  | X |  |  |  |  |
| Medical Director discusses with ARNP assessment and management of each case, reviews and signs medical chart, and then chart is scanned into Cerner. |  | X |  |  |  |  |
| Medical management is provided case by case, following the updated version of the HIV perinatal guidelines, ACOG, CDC and ASCCP guidelines. |  | X |  |  |  |  |

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| **Prescriptions, Ultrasounds, Referrals** | MD | NP | RN | ES | HLS | MA |
| Prescriptions are sent electronically to the pharmacy by NP or printed out and given to the patient. |  | X |  |  |  |  |
| RN ensures that Medicaid/insurance will cover the costs of the prescription(s) otherwise ADAP is used. RN, with NP approval, can complete and obtain prior authorization for medications as needed. |  |  | X |  |  |  |
| Ultrasound orders are entered into Cerner by NP and scheduled by JMH staff for the same day of the visit or for the day that is needed and more convenient for the patient. |  | X |  |  |  |  |
| RN will follow-up if problems arise with Ultrasound appointments. |  |  | X |  |  |  |
| Patients are referred to Nutritionist, Dental, Ophthalmology, HEAL, Recovery Clinic, Fetal Surveillance (ATU) and other medical specialties as needed. If referrals or consults are needed, ARNPs enter request in Cerner. RN makes sure that appointment has been made and follows-up patient’s compliance with consult or referral. |  | X | X |  |  |  |
| RN completes paperwork and communicates with pharmacy and insurance companies as needed to obtain prior authorization. |  |  | X |  |  |  |

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| **Provide Patient Education** | MD | NP | RN | ES | HLS | MA |
| HIV, obstetrical and general counseling is provided by Medical Director, ARNPs and RN. Childbirth educator offers perinatal classes (adapted for HIV patients) and provides educational materials to the patient. Childbirth classes are available during the pregnancy on the same day of the prenatal visits. | X | X | X |  |  |  |

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| **Psychological Evaluation** | MD | NP | RN | ES | HLS | MA |
| Psychological evaluation and psychotherapy are available for all patients in the same clinical area. The psychological evaluation is usually done at the second visit except when after initial assessment an acute or uncontrolled chronic psychological problem is identified. In these cases, the evaluation happens at the first visit, immediately after patient is seen by clinical provider. If there are no immediate concerns, an appointment with the psychologist is scheduled for the next visit. Psychiatric services are also available if needed. | X |  |  |  |  |  |

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| **Interview with Registered Nurse** | MD | NP | RN | ES | HLS | MA |
| The patient meets with the RN at the initial visit and during the following visits as needed for coordination of services, patient education and for to support adherence to medications. |  |  | X |  |  |  |
| NP and RN will visit patients during admission to the hospital/triage or postpartum |  | X | X |  |  |  |
| Close cases after 6 weeks postpartum visit |  |  | X |  |  |  |

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| **Schedule Next Visit** | MD | NP | RN | ES | HLS | MA |
| Plan for return visits is based on individual needs and risk assessment. In an uncomplicated pregnancy, the follow-up visits are schedule every 4 weeks until 24 weeks, every 2 weeks from 25 – 36 weeks and every week after 36 weeks until delivery. ARNP enters the order in Cerner for the next visit. JMH staff schedule the next appointment while the patient is still at the clinic. |  | X |  |  |  |  |
| RN conducts a reminder phone call 2-3 days prior to the next visit. |  |  | X |  |  |  |

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| **Home Visit** | MD | NP | RN | ES | HLS | MA |
| If the patient cannot be contacted and misses two appointments to PRIM, a home visit is requested with the HLS. Two staff members (RN, MA, HLS) visit the patient. If the patient still cannot be contacted, FDOH is notified. |  |  | X |  | X | X |

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| **Obtaining Lab Results and / or other Diagnostic Tests** | MD | NP | RN | ES | HLS | MA |
| If labs or diagnostic tests are performed at the clinic, the ARNP checks the message box that appears in Cerner which indicates results are ready. For outside labs (ie Quest, LabCorp), the ARNP logs into the lab’s website to access results and also submit them for scanning in Cerner and CAREWare. |  | X |  |  |  |  |
| Safety / monitoring labs are requested as per guidelines and individualized clinical evaluation. |  | X |  |  |  |  |
| Results are reviewed and discussed with the Medical Director as needed. | X |  |  |  |  |  |
| Patients are notified about results in the following visit or before by phone or letter if needed and depending of each case. |  | X |  |  |  |  |
| If cervical Pap smear is abnormal, patient will be scheduled for colposcopy. |  | X |  |  |  |  |
| If STI screening is positive, patient receives counseling and treatment as per CDC guidelines and FDOH is notified. |  | X |  |  |  |  |
| RN enters the following data into CW: pap smear, syphilis test, gonorrhea and chlamydia culture, current medications, information of pregnancy, each prenatal and post-partum visit, and newborn delivery details. |  |  | X |  |  |  |

* 1. **Components of 1st Trimester Visits**
     1. Assess maternal wellness
        1. Review and updated medical history
        2. Perform physical, obstetric, pelvic exam as indicated
        3. Vital signs
        4. Weight gain
        5. Fundal height
        6. General / focus exam as needed
     2. Assess fetal wellness
        1. Fetal Heart Tones
        2. Cell-free fetal DNA testing, if indicated offer to patient and if patient consent
        3. Other fetal evaluation as indicated
     3. Labs and diagnostic tests
        1. Review results of previous laboratory or diagnostic tests.
        2. Request labs or diagnostic test as per guidelines or as needed.
     4. Assessment and management of risks factors or problems particularly those related to the first trimester: vaginal bleeding, spontaneous abortion, urinary tract infection, STIs, co-morbidities (ie. Pre-gestational diabetes, chronic hypertension) and others.
     5. Patient education pertinent to first trimester
        1. Discussion of options: continue pregnancy, termination, adoption.
        2. Risk of perinatal transmission, cART, adherence, resistance, disclosure among others.
        3. Common changes and discomforts during pregnancy
        4. Nutritional needs, body mass index and weight management.
        5. Importance of compliance with treatment, labs and diagnostic testing, and with appointments
        6. Other pertinent patient education depending of each case
     6. Plan for return visits is based on individual needs and risk assessment. If is an uncomplicated pregnancy the follow-up visits are schedule every 4 weeks until 24 weeks.
     7. Results, assessment and management discussed with Medical Director.
     8. Notes for each visit are written in the JHS Obstetrical follow-up form.
     9. Medical Director reviews and document in patient’s chart, then chart is scanned to Cerner.
     10. Obstetrical visit is enter in CW and labs and medications if applicable.
  2. **Components of 2nd Trimester Visits**
     1. Assess maternal wellness
        1. Review and updated medical history
        2. Perform physical, obstetric, pelvic exam as indicated
        3. Vital signs
        4. Weight gain
        5. Fundal height
        6. General / focus exam as needed
     2. Assess fetal wellness
        1. Fetal Heart tones
        2. Fetal quickening / movements
        3. Screening for neural tube defects if patient consent
        4. Refer to additional testing if needed (ie. Fetal echocardiogram)
     3. Labs and diagnostic tests.
        1. Labs at 24 – 28 weeks, including but not limited to: gestational diabetes screening, safety labs, monitoring T-cells and viral loads, HIV genotype if indicated at this time and other pertinent labs.
        2. OB ultrasound at 17-19 weeks of gestational age for fetal anatomy. Follow-up ultrasounds as needed.
     4. Assessment and management of risks factors or problems particularly those related to the second trimester: vaginal bleeding, fetal anatomy and genetic screening, placental position, premature labor, co-morbidities (ie. Gestational diabetes) and others.
     5. Patient education pertinent for second trimester.
        1. Review HIV counseling, cART adherence, compliance with appointments.
        2. Second trimester precautions (ie. PTL signs and symptoms).
        3. Pregnancy complications or co-morbidities (ie. Gestational Diabetes, CHTN)
        4. Family planning
        5. Other pertinent patient education depending of each case.
     6. Plan for return visits is based on individual needs and risk assessment. If is an uncomplicated pregnancy the follow-up visits are schedule every 2 weeks.
     7. Results, assessment and management discussed with Medical Director.
     8. Notes for each are written in the JHS Obstetrical follow-up form.
     9. Medical Director reviews and document in patient’s chart, then chart is scanned to Cerner.
     10. Obstetrical visit is enter in CW and labs and medications if applicable.
  3. **Components of 3rd Trimester Visits**
     1. Assess maternal wellness
        1. Review and updated medical history
        2. Perform physical, obstetric, pelvic exam as indicated
        3. Vital signs
        4. Weight gain
        5. Fundal height
        6. Screening for Streptococcus Group B (GBS) and GC/CT at 35 weeks.
        7. General / Focus exam as needed
     2. Assess fetal wellness
        1. Fetal heart tones
        2. Fetal movements
        3. Evaluation of fetal growth
        4. Patient send for fetal surveillance to ATU as needed.
     3. Labs and diagnostic tests.
        1. Third trimester labs are requested at 32- 34 weeks of gestational age, including but not limited to syphilis IgG, Hepatitis B surface antigen, Hepatitis C Virus antibody, CBC, AST, ALT, T-cells and Viral load.
        2. Cultures at 35 weeks: GBS, GC/CT.
        3. HIV Viral load at 36 weeks.
        4. OB US at 32-34 weeks for estimate fetal growth. Follow-up OB US as needed.
     4. Assessment and management of risks factors or problems particularly those related to the third trimester: vaginal bleeding, premature labor, fetal growth restriction, hypertension, co-morbidities and others.
     5. Patient education pertinent for third trimester.
        1. Plan for delivery
        2. Labor and warning signs and symptoms, fetal movement counts
        3. Review Family Planning
        4. Review contraindication of breastfeeding and pre-masticated food
        5. Review plans for continuity with HIV care and infant care
        6. Other pertinent patient education based in each case
     6. Plan for return visits is based on individual needs and risk assessment. If is an uncomplicated pregnancy the follow-up visits are schedule every 2 weeks until 36 weeks and every week until delivery.
     7. Results, assessment and management discussed with Medical Director.
     8. Notes for each visit are written in the JHS Obstetrical follow-up form.
     9. Medical Director reviews and document in patient’s chart, then chart is scanned to Cerner.
     10. Obstetrical visit is enter in CW and labs and medications if applicable.
  4. **Visits to OB triage and Admissions**

If the patient is admitted to the hospital or if is in triage, the RN or the ARNP visit the patient during hospitalization.

* 1. **Labor and Delivery**
     1. Prenatal records are available electronically in Cerner and paper records are available on the labor floor 24/7
     2. If the patient is candidate for trial of labor, she will present to OB triage when she presents labor signs at symptoms; Medical Director is notified when the patient arrives.
     3. After evaluation, a decision is made if the patient will be admitted to LD floor or discharge home
     4. If the patient needs induction of labor, she will come to LD floor and present for induction the day that has been scheduled.
     5. If the patient is scheduled for Cesarean section, she will come to LD floor on the date that has been scheduled.
     6. ARNPs report the delivery to Pediatric Special Immunology and to the Manager of the Comprehensive AIDS Program sending a secure email.
     7. ARNPs and RN visit the patient on the LD, recovery or post-partum floor.
     8. RN enters the information about delivery in CareWare.
     9. Before the patient is discharged, counseling is provided regarding continued treatment for her and the newborn, contraindication of breastfeeding, breast care, post-partum care and warning signs and symptoms, appointment at the Pediatric Screening Clinic for the newborn, postpartum appointment for her, family planning and other pertinent issues.
     10. Patient is discharged with reliable birth control method (if patient agrees) and with prescriptions for mother and newborn. Medication is provided for newborn.
     11. Case manager, Social worker, Psychology, Psychiatric services are available if needed.
     12. WIC office is in the same post-partum floor and patient can see them before discharge.
  2. **Postpartum**
     1. Patient is scheduled and seen at 6 weeks postpartum but may be seen before, at 2-3 weeks postpartum if needed.
     2. Confirmation that patient is compliant with infant screening visits at Pediatric SI.
     3. Follow-up family planning. If patient still is not on a reliable birth control method, contraceptive counseling is given and patient is encouraged to initiate a birth control method.
     4. Follow-up particular post-partum issues, review post-partum Labs / referrals or consults (ie. Anemia, hypertension or other co-morbidities) and medications.
     5. Labs as needed (ie. f/u pap smear if abnormal during pregnancy, CBC if significant anemia post-delivery)
     6. Patient is referred to primary care in our facility or community clinics depending on prior provider, medical insurance and patient decision.
     7. Results, assessment, management, referrals discussed with Medical Director.
     8. Notes for post-partum visit are written in the JHS Post-partum form.
     9. Medical Director reviews and document in patient’s chart, then chart is scanned to Cerner.
     10. Post-partum visit is enter in CW.
     11. Monitor that patient has appointment with HIV specialist.
     12. RN prepares case closure form and submits it to CQM Manager.

1. **DOCUMENTATION**
   1. **Maintenance of SOPs**

The signed originals of this SOP will be scanned and stored in the J drive (shared drive for the Division of Research and Special Projects).

1. **REFERENCES**
   1. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. <http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf>
   2. The American College of Obstetricians and Gynecology. <http://www.acog.org/Resources-And-Publications/>
   3. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2010. [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5912a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5912a1.htm%20)
   4. American Society for Colposcopy and Cervical Pathology. <http://www.ASCCP.org/Consensus2012>
2. **TEMPLATES – N/A**
3. **REVISION HISTORY**

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| --- | --- | --- | --- |
| Effective Date | Revision Date | Author | Description of Changes |
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**SIGNATURES**

Prepared by: JoNell Potter, PhD Date: \_\_\_\_\_\_\_\_\_\_\_\_

Director, Division of Research and Special Projects

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Signature

Approved by: Ira Karmin, MD Date: \_\_\_\_\_\_\_\_\_\_\_\_

Chairman, Department of OB/GYN

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