Pregnancy Testing (HRPP 3.10)

Description:

This policy describes UNMC's requirements for determining how and when pregnancy testing should be performed on subjects who are of childbearing potential enrolled in protocols that describe pregnancy as an exclusion criteria.

General Considerations:

- Protocols that describe pregnancy as an exclusion criterion must describe how the pregnancy status will be determined
- If the **research intervention is potentially harmful to a fetus**, the protocol must requite pregnancy testing prior to the intervention
  - **Testing:**
    - Default testing should be urine unless blood is already being drawn for another reason *(in this case, serum qualitative testing is acceptable)*
    - Acceptable test results are those performed at a healthcare facility
- If the **research intervention is not expected to cause harm to the fetus**, the subject may self-report their pregnancy status
- A negative pregnancy test **within 7 days prior to the intervention** is considered current
- For ongoing interventions, testing should be done at a frequency consistent with clinical practice
- **Minor Subjects:**
  - Should be informed during the consent/assent process that pregnancy test results will be shared with their parent/guardian
  - Should be given test results privately followed by disclosure to their parent/guardian
- **Charging for pregnancy testing:**
  - Subjects should be informed of whether they will be charged
  - Subjects may NOT be charged for pregnancy testing if:
    - The protocol requires pregnancy testing but the intervention is not expected to cause fetal harm

- A person who is not of childbearing potential is tested

- **Positive Pregnancy Test:**
  - The subject should be:
    - Referred to their primary care provider
    - Offered the option to have study information shared with their provider if any intervention occurred before the positive test

- **Consent:**
  - The informed consent form and informed consent/assent process must include the following:
    - How often pregnancy testing will be done
    - Whether subjects will be removed from the study if they become pregnant