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 include pregnancy testing prior to the intervention.

- Should be a urine test unless blood is being drawn for another reason.
- Home pregnancy tests not acceptable.
- 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 and not more than monthly.

If the research intervention is not expected to cause harm to the fetus, the subject may self-report their pregnancy status.

Subjects should be informed whether they will be charged for pregnancy testing.

- If the protocol requires pregnancy testing but the intervention is NOT expected to cause fetal harm, the subject should NOT be charged.
- (Though strongly discouraged) if females not of childbearing potential are tested for pregnancy, they may NOT be changed.

Consent:

The ICF and informed consent/assent process must include the following:

- Frequency of pregnancy testing.
- How often subjects will be informed of the results.
- Whether or not subjects will be removed from the study if they become pregnant.
- If a subject is a minor, they should be informed that their parent/guardian will be informed of the results.

Positive Pregnancy Test:

If a subject has a positive pregnancy test:

- Refer them to their primary care physician.
- If the subject received any study interventions prior to the positive test, the study information should be sent to their primary care physician.