3.10 Pregnancy Testing

Last Revised: 1/8/2018

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization'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 criterion.

2.0 Policy

It is the policy of the Organization that when women of childbearing potential are enrolled in protocols which include a pregnancy exclusion criterion, the protocol must have procedures in place for either pregnancy testing or self-reporting depending on the teratogenic risk.

3.0 Definition

- **3.1.** Woman of childbearing potential (WOCBP) for the purpose of this policy is a woman who has begun menstruating and not entered menopause. Women who are sterile due to history of hysterectomy, bilateral oophorectomy, or radical pelvic irradiation are not considered females of childbearing potential.
- **3.2.** Menopause for the purpose of this policy is defined as lack of menses for 12 months in the absence of any reversible medical condition which could produce amenorrhea.

4.0 Procedures

- **4.1.** Protocols that describe pregnancy as an exclusion criterion must describe how pregnancy status will be determined.
- **4.2.** Protocols that include an intervention considered potentially harmful to a fetus must include pregnancy testing prior to initiating the intervention(s).
- **4.3.** If pregnancy testing is required (as indicated in Section 4.2 above), testing should be performed on urine unless blood is being drawn for another reason. In that case, serum qualitative pregnancy testing can be performed.
    - **4.3.1.** Quantitative testing is not indicated for the purposes of this policy.

    - **4.3.2.** Acceptable test results are those performed at Nebraska Medicine, BMC, CHMC, or a documented result from the subject's provider.
    - **4.3.3.** Home pregnancy test results are not acceptable.
- **4.4.** Protocols that describe pregnancy as an exclusion criterion, but are not expected to cause fetal harm, may use subject self-report of pregnancy status.
- **4.5.** A negative pregnancy test within 7 days prior to the intervention of interest should be considered current, consistent with Nebraska Medicine Pregnancy Testing Policy (MS72). For ongoing interventions or exposures, testing should be done at a frequency consistent with clinical practice (and not more often than monthly).
- **4.6.** The informed consent/assent process and the ICF must include:
    - **4.6.1.** How often pregnancy testing will be done.
    - **4.6.2.** How often subjects will be informed of results.
    - **4.6.3.** Whether subjects will be removed from the study if they become pregnant.
- **4.7.** Minor subjects should be informed during the consent/assent process and in the ICF that their parent/guardian will be informed of the test results.
- **4.8.** Subjects should be informed of whether they will be charged for pregnancy testing:
    - **4.8.1.** For protocols that require pregnancy testing, but are not expected to cause fetal harm, subjects may not be charged for pregnancy testing.
    - **4.8.2.** The IRB strongly discourages pregnancy testing of females who are NOT of childbearing potential. However, if such subjects will be tested, they may not be charged for this test.
- **4.9.** Subjects should be given pregnancy test results privately. Minors should be given pregnancy test results privately followed by disclosure by the research team to the subject's parent or guardian.
- **4.10.** Any subject with a positive pregnancy test should be referred to her primary care physician to review the positive test result. Subjects should be offered to have study information sent to their primary care physician if the subject received any intervention prior to the positive pregnancy test.

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