

RDRC SOP on Pregnancy Testing

The regulations governing Radioactive Drug Research Committees (RDRC) found at 21 CFR 361.1 (d) (5) include the following requirement:

Each female research subject of childbearing potential shall state in writing that she is not pregnant, or, on the basis of a pregnancy test, be confirmed that she is not pregnant, before participating in any study.

If the pregnancy test is positive, please report this to the RDRC with the action taken (RDRC@ucdenver.edu.)

In order to assure that this requirement is met, the RDRC will require that the PI complete and document this discussion with each female subject enrolled in their study. This will be accomplished through the use of the RDRC Case Report Form (CRF) for Pregnancy Testing. The form is appended to this document.

History of SOP	Date
Initial approval	12/16/15
Review by the RDRC	
Re-review:	

Study ID: _____

Study Title: _____

PI: _____

The regulations governing radioactive drug research require that a woman of childbearing potential state in writing that she is not pregnant, or, on the basis of a pregnancy test, be confirmed as not pregnant, before she may participate in an RDRC study.

The FDA recommends that the absence of pregnancy be confirmed by a pregnancy test.

Lack of pregnancy in women of childbearing potential confirmed by a negative pregnancy test via: Urine test Blood test

Date of test : _____

(If the pregnancy test is positive, please report this to the RDRC with the action taken RDRC@ucdenver.edu).

Postmenopausal or surgically sterile women are not regarded as having childbearing potential. Postmenopausal is defined as 12 months of spontaneous amenorrhea, 6 months of spontaneous amenorrhea with serum FSH levels >40 mIU/mL, or 6 weeks postsurgical bilateral oophorectomy with or without hysterectomy.

The FDA recommends that women of childbearing potential use a reliable form of contraception, such as an IUD, hormonal contraception, tubal ligation, partner's vasectomy, latex condom, diaphragm, or cervical cap throughout the at-risk period. **Discussed with study subject: Study team member initials and date:** _____

The FDA recommends that IUD use and hormonal contraception begin at least 1 month before radioactive drug administration. **Discussed with study subject: Study team member initials and date:** _____ The FDA recommends that women not become pregnant after exposure to a radioactive drug until the potential fetal dose from remaining radionuclide(s) is < 1 mSv (<100 mrem).

Discussed with study subject: Study team member initials and date:

I affirm that I am not pregnant.

Subject Signature and Daterinted Name