



## OPRS NEWS

The following news update from OPRS highlights a revised OPRS forms and a national shortage of radiopharmaceuticals and protocols deviations.

### OPRS NEWS Update

1/2/08

1. National Shortage of Radiopharmaceuticals and Protocol Deviations
2. Revised OPRS Forms

#### 1. National Shortage of Radiopharmaceuticals and Protocol Deviations:

Due to the current national shortage of radiopharmaceuticals, protocols requiring Nuclear Medicine and Nuclear Cardiology imaging may be affected. The DFCI IRB has determined that any deviations which occur as a result of this national shortage of radiopharmaceuticals should be reported to the DFCI IRB using the Minor Deviation/Violation Log.

In contrast to the IRB's policy regarding the reporting of 3 or more deviations/violations of the same type, the IRB will not require that 3 or more deviations/violations resulting from this shortage be reported as a major deviation to the protocol. In these cases, deviations/violations should continue to be reported to the DFCI IRB on the Minor Deviation/Violation log.

#### 2. Revised Forms:

*Please note all OPRS forms must be downloaded from the OPRS website at the time of completion, otherwise the form submitted may be out of date and delay IRB review.*

**1. Request to Add Site/Remove Site Form:** The previous Add Site form has been revised to include a section to be completed in order to remove a site. Additional related questions have also been added to the form including the status of subjects at the site that is going to be removed. The form is also now on the most recent template and incorporates a few minor editorial changes. The revised form is dated 11/13/07 in the footer and should be used with all submissions to the OPRS.**2. The Deviation/Violation Log:** We have added to the form a "Added to Log Date" column in order for study teams to document when the reported event was added to the form. There are also several minor editorial changes made to this log. This new log version has a modified date of 11/14/07 in the footer and should be used with the completion of all new logs.**3. The Closure/Re-Open to**

**Enrollment form:** The Closure/Re-Open Form was revised to fix question four so the reason for re-opening a trial can now be included in the form as required. The revised form is dated 11/07/07 in the footer and should be used for all submissions to the OPRS.

**Thank you!**

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