



OPRS NEWS

DFCI Policy on Reporting Deviations/ Violations/ Exceptions to OPRS

Listed below is an updated list of our OPRS staff. Many changes have been made, so please review this list and keep it handy for your convenience. This list can also be found on our website at:

<http://www.dfhcc.harvard.edu/clinical-research-support/office-for-the-protection-of-research-subjects-oprs/contact-info/>

The DFCI policy on reporting deviations/violations/exceptions to OPRS has been revised as follows:

"A deviation/violation/exception does not need to be reported when it is a minor deviation in scheduling due to a state or federal holiday, inclement weather or circumstances beyond the control of a subject or investigator. Any deviation that is not reported for one of these reasons must be noted in the subject's medical and research record. Note: **This does NOT include conflicts with a subject's work schedule or planned vacation.**

Any deviation/violation/exception that might affect the potential risk or benefit to subjects in any way or have any impact on the integrity of the science must be report to OPRS."

The information above is a short excerpt from the revised policy. Please review the policy carefully.

Thank you!

For further information, contact:

The Office for the Protection of Research Subjects
20 Overland Street
2nd Floor
Boston, MA 02115
617-632-3029

**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH**

TITLE: Reporting Unexpected Events (Deviations/Exceptions/Violations) to the DFCI IRB for Approved Protocols	
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SOP #: PM-407

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Applicable Regulations

& Guidelines:

45 CFR 46.103(b)(4)(iii) and 21 CFR 56.108(a)(4)

Other References:

DFCI IRB Protocol Deviation/Violation/Exception Request, The Guide to Human Research Activities

Responsible Personnel:

DF/HCC Principal Investigators (PI) or study staff designee, Office for the Protection of Research Subjects (OPRS)

Policy Statement:

PIs are responsible for submitting the appropriate form to the IRB in the event that a deviation, violation, or exception occurs.

Procedure:

- 1) Please see The Guide to Human Research Activities posted on the CTEO website: <http://www.dfhcc.harvard.edu/clinical-research-support/clinical-trials-education-office-cteo/>
- 2) A deviation/violation/exception does not need to be reported when it is a minor deviation in scheduling due to a state or federal holiday, inclement weather or circumstances beyond the control of a subject or investigator. Any deviation that is not reported for one of these reasons must be noted in the subject's medical and research record. Note: This does NOT include conflicts with a subject's work schedule or planned vacation.
- 3) Any deviation/violation/exception that might affect the potential risk or benefit to subjects in any way or have any impact on the integrity of the science (e.g. conclusions that can be drawn from the study) must be reported to the DFCI IRB.

Original Approval Date: CLINPOC 2/03

Revision Dates: CLINPOC 5/26/05, 1/23/06
