

Office for Human Research Studies

New Forms Posted on OHRS Website

Please be advised that two new forms have been posted to the OHRS website.

Report of Unanticipated Problems Involving Risks to Subjects or Others.

This form is for reporting an unanticipated problem involving risks to subjects or others at either (1) DF/HCC or (2) outside Multi-Center sites where a DF/HCC investigator is the overall PI. If any protocol and/or consent form changes are required as a result of this reported event, this report form should be submitted as an attachment to an Amendment Form. Please note that if the unanticipated problem is also an adverse event, please report the incident using an adverse event report form.

Request for the DFCI IRB to Cede IRB Review. This form should be submitted to request that the DFCI IRB rely upon the IRB of another institution for new and continuing studies. If approved, an IRB Authorization Agreement must be entered into by the institutions. Please note that if any DFCI or DF/HCC systems will be involved in the research (e.g., QACT for subject registration; research pharmacy; nursing) the research must be approved by the DFCI IRB. Additionally, if the research is cancer-related, the research must be approved by the DF/HCC scientific review committee and the DFCI IRB.

The forms are available from the OHRS website: <http://www.dfhcc.harvard.edu/ohrs>.

Please do not hesitate to contact OHRS if you have any questions or require additional information.

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(Please note: OPRS is now the Office for Human Research Studies.)