

Office for Human Research Studies

OHRs Forms & Website Updates

Please be advised of the following updates to the OHRs website:

New Forms and Resources

- **Risk Language for Consent Forms.**
The "Common Language for Risks and Events Spreadsheet" has been replaced by a searchable web-based database titled "Common Language for Risks and Events". A username and password are not required to access the application. Please also refer to the related Information Sheet for additional information about this database and how to use it at: [Guidance Document: Common Language for Risks and Events](#).

Please note: The application can be directly accessed at https://oprs.dfci.harvard.edu/AE/ae_search.asp or can be found at <http://www.dfcc.harvard.edu/ohrs> under "Consent Documents".

Revised Forms and Resources

- **Endorsement Form.**
The Endorsement Form has been revised to include requests for estimated accrual at each participating DF/HCC institution and for whether the study targets a rare disease.

Please note: The current version of the Endorsement Form is dated 04/14/2009. After May 1, 2009, older versions of the form will not be accepted by OHRs. The form can be found at <http://www.dfcc.harvard.edu/ohrs> under "Submitting a New Protocol".

- **DFCI Protocol Front Sheet.**

The protocol front sheet has been revised to indicate that Emerson Hospital is no longer a DF/PCC affiliate but continues a relationship with MGH Radiation Oncology.

Please note: The current version of the Front Sheet is dated 04/14/2009. After May 1, 2009, older versions of the form will not be accepted by OHRs. The form can be found at <http://www.dfcc.harvard.edu/ohrs> under "After Activation Forms" and

"Submitting a New Protocol".

- **Deviation/Violation/Exception Policy.**

The Deviation Policy, found at <http://www.dfhcc.harvard.edu/ohrs> under "OHRs Information Sheets" has been modified to explain that events reported for any protocol approved and taking place at multiple DF/HCC institutions is still considered one protocol. The revised policy is dated 4/14/2009.

- **Deviation/Violation Log.**

The Deviation/Violation Log has been modified with formatting changes and additional space for deviations to be logged.

Please note: The current version of the Endorsement Form is dated 04/14/2009. After May 1, 2009, older versions of the form will not be accepted by OHRs. The form can be found at <http://www.dfhcc.harvard.edu/ohrs> under "After Activation Forms"

- **Serious Adverse Event (SAE) Reporting Form.**

The Serious Adverse Event form has been modified to add instructions for multi-center sites reporting SAEs where a local SAE form is available for submission to OHRs.

Please note: The current version of the Serious Adverse Event Reporting Form is dated 04/14/2009. After May 1, 2009, older versions of the form will not be accepted by OHRs. The form can be found at <http://www.dfhcc.harvard.edu/ohrs> under "After Activation Forms"

If you have any questions, please do not hesitate to contact us.

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