

Office for Human Research Studies

OHRs Forms & Information Sheet Changes

Dose Escalation Changes in Phase I Approved Research

- ***New: Implementing Dose Escalation Changes in Phase I Approved Research***
A new OHRs Information Sheet has been created to clarify how to implement a dose escalation change in an approved Phase I or Phase I/II protocol that is actively enrolling to the Phase I portion of the protocol. This does not apply to non-Phase I research.

Please note: This Info Sheet was created on 07/01/09 and can be found at:

<http://www.dfhcc.harvard.edu/clinical-research-support/office-for-human-research-studies-ohrs/ohrs-information-sheets/>

- ***Updated: Guidance on Alert Pages***
The Guidance on Alert Pages Information Sheet was updated to include additional information regarding the use of a dose escalation table on an Alert Page. Please refer to the new Info Sheet on Implementing Dose Escalation changes for further information.

Please note: This Info Sheet was created on 07/01/09 and can be found at:

<http://www.dfhcc.harvard.edu/clinical-research-support/office-for-human-research-studies-ohrs/ohrs-information-sheets/>

- ***Updated: Closure/Re-Open to Enrollment Form***
Changes were made to the Closure/Re-Open Form correspond with the new Info Sheet on Implementing Dose Escalation Changes in Phase I Approved Research. Number 3, in part B of the form has been revised to ask if any portion of the study, an Arm or Phase for example, is closing to enrollment and removed the earlier question about a change in cohort.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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".

Protocol Endorsement

- **Updated: Endorsement Form**

The Endorsement Forms now requests an explanation as to why not all DF/HCC sites are participating in the study. This question has been removed from the new project application forms to avoid redundancy.

Please note: The current version of the Endorsement Form is dated 07/01/2009. Beginning August 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 "Submitting a New Protocol".

- **Updated: Guidance on Completing the Endorsement Form**

The Guidance on Completing the Endorsement Form has been revised to reflect that research that is not cancer related does not require the submission of an endorsement form. Additionally, an endorsement form is not required for non-clinical research involving medical record reviews, social & behavioral research and use of already existing specimens. However, research involving the prospective collection of human specimens will require an endorsement form, but no biostatistician signature is required.

Please note: The revised guidance can be found at <http://www.dfhcc.harvard.edu/ohrs> under "Submitting a New Protocol" and "OHRS Information Sheets".

- **Updated: Program Leader List for Signing Endorsement Forms**

This list has been updated to reflect current designated signatories for the endorsement forms which accompany new protocol applications.

Please note: This list can be found on the CRU website at <http://www.dfhcc.harvard.edu/clinical-research-support/clinical-research-unit-cru/> under "Contacts".

- **Updated: Front Sheet**

Section 4 of the Front Sheet has been updated to include questions about the applicable disease/discipline based program as well as to add hormone therapy to the list of protocol interventions. Additionally, Section 5 has been revised to clarify that this section also applies to medical record reviews and tissue collections. Finally, Section 6 has been updated to list DFCl at Londonderry and Milford as satellite sites, as well as MGH's satellite at North Shore. Please also see the *Guidance on Completing the Front Sheet* which has also been updated.

Please note: The current version of the Front Sheet is dated 07/01/2009. Beginning August 1, 2009, older versions of the form will not be accepted with New Protocol Applications. We ask that the new version of the Front Sheet be submitted along with future amendments. The form can be found at <http://www.dfhcc.harvard.edu/ohrs> under "Submitting a New Protocol" and "After Activation Forms."

- **Updated: Guidance on Completing Front Sheets**

The Guidance on Completing Front Sheets has been revised to reflect recent updates as describe above.

Please note: The revised guidance can be found at <http://www.dfhcc.harvard.edu/ohrs> under "Submitting a New Protocol", "After Activation Forms", and "OHRS Information Sheets".

- **Updated: New Project Application - Clinical Trials**

This form has been revised to no longer request an explanation about why not all DF/HCC

sites are participating. This request is now incorporated in the endorsement form. .

Please note: The current version of this form is dated 07/01/2009. Beginning August 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 "Submitting a New Protocol".

- **Updated: New Project Application - Medical Record Review**

This form has been revised to no longer request an explanation about why not all DF/HCC sites are participating. This request is now incorporated in the endorsement form. We have also updated the formatting of this form so that is more consistent with the clinical trials application form.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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 "Submitting a New Protocol".

- **Updated: New Project Application - Social and Behavioral Research**

This form has been revised to no longer request an explanation about why not all DF/HCC sites are participating. This request is now incorporated in the endorsement form. We have also updated the formatting of this form so that is more consistent with the clinical trials application form.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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 "Submitting a New Protocol".

- **Updated: New Project Application – Research Use of Human Material/Tissue**

This form has been revised to no longer request an explanation about why not all DF/HCC sites are participating. This request is now incorporated in the endorsement form. We have also updated the formatting of this form so that is more consistent with the clinical trials application form.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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 "Submitting a New Protocol".

- **Reminder: When submitting a new protocol to the OHRS, please ensure that all submissions include both electronic and hardcopy versions of all documents.**

Minor Updates to OHRS Forms

- **Updated: Serious Adverse Event Form**

Changes were made to the instructions of the Serious Adverse Event (SAE) form to state that investigators are responsible for reporting SAEs to their risk management departments as applicable.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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".

- **Updated: Major Deviation/Exception/Violation Form**

Changes were made to the instructions of the Major Deviation/Violation/Exception form to state that investigators are responsible for reporting major other events to their risk management departments as applicable.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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".

- **Updated: Amendment Form**

Editorial changes were made to part B to include data collection as a type of change.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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".

- **Updated: Continuing Review Form**

Changes were made to the Continuing Review Form to request the model consent form for cooperative group studies be submitted by the study team for review.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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".

- **Updated: New Project Application – Request for Exemption from IRB Review or Determination that Activity is Not Human Research**

A checklist for the required documentation that should be submitted with this form has been added to the last page of this form. Please note that such requests must be accompanied by front sheet and a signed statement of the overall principal investigator. Editorial changes were also made to include a box after question 9b, which was previously missing.

Please note: The current version of this form is dated 07/01/2009. Beginning August 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 "Submitting a New Protocol".

- **Updated: PI-Site PI Change, Research Team Update, Statement of Investigator, and Statement of Study Team Member forms**

Additional fields has been added to these forms which will eliminate OHRS' need to request study staff to fill out Rex – New Profile forms.

Please note: The current versions of these forms are dated 07/01/2009. Beginning August 1, 2009, older versions of these forms will not be accepted by OHRS. These forms can be found at <http://www.dfhcc.harvard.edu/ohrs> under "Submitting a New Protocol" and "After Activation Forms".

Model Consent Template and Related Guidance on Obtaining Consent

- **Updated: Biomedical Informed Consent Document.**

The model informed consent document has been updated. Please see the "consent log" for an itemized list of the recent changes.

Please note: The current version of this form is dated 07/01/2009. Beginning August 1, 2009, older versions of the form will not be accepted by OHRS. The new model template should be used for new submissions submitted under "Consent Documents".

- **Updated: 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.dfc.harvard.edu/AE/ae_search.asp or can be found at <http://www.dfhcc.harvard.edu/ohrs> under "Consent Documents".

- **Updated: Instructions for Obtaining and Documenting Informed Consent of Non-English-Speaking Subjects**

The Information Sheet on Obtaining and Documenting Informed Consent of Non-English-Speaking Subjects has been updated to specify that if a study contains optional studies, the subject is assumed to not have consented to these unless the short form has an additional section included to capture the subject's responses to participation in those Optional Studies. This Info Sheet was updated on 07/01/09.

- **Updated: Consent for Continued Participation in a Research Study by a Young Adult who has Reached Age 18**

The Information Sheet on Consent for Continued Participation was updated to note that a waiver of re-consent may be requested of the IRB by the study team where it is highly unlikely that the study team will have any contact with the subjects at the time they reach the age of 18. This Info Sheet was updated on 07/01/09.

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

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