



OPRS NEWS

The following news update from OPRS highlights a new priority list form and changes to several other forms.

OPRS NEWS Update 10-4-07

1. **New Priority List Form**
2. **Updated New Clinical Trials Project Application Form**
3. **Template Language to be Included in Consent Forms**
4. **Radiation Safety Protocol Screening Form Administrative Changes**
5. **Statement of Principal Investigator & Study Team Member Form Changes**
6. **Closure Form Changes**

1. New Priority List Form

Under the NCI core grant requirements, prioritization of protocols is critical and must be approved by the Scientific Review Committee. In order to comply with the NCI requirements, the SRC must review changes to a priority list. The changes must be confirmed as acceptable by the disease program leader.

A new form for priority list additions, changes and removals has been implemented to serve this purpose. This form can be found on our website under "Forms and Instructions." We have also updated the new application form and closure form to facilitate management the prioritization of protocols.

This form is located here:

http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/New_Submission/Priority_list_change_form.doc

2. Updated New Clinical Trials Project Application Form

The New Clinical Trials Project Application Form has several updates including:

- Addition of *Subject Compensation* section
- Change to *Recombinant DNA* section
- Change to *Handling of Biological Specimens* section
- Change to *Use of Tumor Imaging Metrics Core* section
- Change to *Multi-Center Studies* section
- Change to *Dana-Farber/Partners Cancer Care Network Affiliates* section
- Addition of *Experience of Overall Principal Investigator* main section which includes two questions about previous Overall PI involvement in clinical trials
- Addition of *Priority List Placement* section
- Change to the *New Application Submission Checklist* at the end of the form
- Change to the "Revised Date" on the footer – be sure to use the New Clinical Trials Project Application Form with the revised date of October 3, 2007

This form is located here:

http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/New_Submission/New_Project_-_Clinical_Trials.doc

3. Template Language to be Included in All Consent Forms

The following template language needs to be included in all consent forms in the "What are the Risks of this Study" section:

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

Please review your consent form(s) for this language and include this template language at the time of your next planned amendment or continuing review submission.

4. Radiation Safety Protocol Screening Form Administrative Changes

The second question in the *Background Information* was changed to clarify "participating" as "performing research scans." The *Revised* date on the footer was also changed to 9/24/07.

This form is located here:

http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/New_Submission/RSC_Screening_Form.doc

5. Statement of Principal Investigator & Study Team Member Form Changes

A question was added in the *Statement of Assurance* section verifying that required training has been completed, the type of training completed and the date of completion. Additional administrative changes were also made to the end of the form. The *Revised* date on the footer was also changed to 9/24/07.

These forms are located here:

<http://www.dfhcc.harvard.edu/clinical-research-support/office-for-the-protection-of-research-subjects-oprs/forms-and-instructions/new-submission-forms/>

6. Closure Form Changes

The Closure Form now has a Priority List Placements section which must be filled out to note all places the protocol is placed on the Priority List. Additional changes to form are the removal of hard copy submissions, copy on floppy disk submissions as well as formatting changes. The *Revised* date on the footer was changed to 9/24/07.

This form is located here:

http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/Post_Activation/Closure-Re-Open_to_Accrual_Form.doc

Please make sure to download any form from the OPRS website before submission to assure you have the most up-to-date form. This will assure your submission is not sent back.

Thank you!

For further information, contact:
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