



OPRS NEWS

The following news update from OPRS highlights new templates, letters and OPRS staff members.

OPRS NEWS ALERT 6- 20- 2006

1. **New Protocol Front Sheet and Related Policy Change: SM-501**
2. **Required Consent Form Template Revisions**
3. **Updated CTSU Letter and Letter for Sponsors**
4. **New OPRS Staff Members**

1. NEW PROTOCOL FRONT SHEET & RELATED DF/HCC POLICY SM-501:

New Protocol Front Sheet: Version 6/06 replaces all former versions of the Front Sheet

[Click here to view new Protocol Front Sheet](#)

Related DF/HCC Policy: SM-501 Obtaining Informed Consent in Human Research Studies

[Click here to view SM-501](#)

2. CONSENT FORM REVISIONS REQUIRED:

On 01/25/2006 an OPRS News email was sent out to the research community regarding changes to the model consent. Included in this email were four changes that were to be made to the consent form of all ongoing studies. These changes are now required for all ongoing studies. A change to the HIPAA language is now also required. Please review the sections of your consent form noted below against the [Model Consent form \(link\)](#) and make these required changes as appropriate.

Please also note that the consent form template is regularly updated, so be sure to always use the most recent version posted on the OPRS webpage.

- a. Update financial contact numbers.

Under the "**What are the costs?**" section, please update the financial services numbers.

[Include only the relevant institutional numbers]

- Dana Farber Cancer Institute: (617) 632-3455
- Massachusetts General Hospital: (617) 726-2191
- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485
- Beth Israel Deaconess Medical Center: (617) 667-5661
- Children's Hospital, Patient Care Coordination Center: (617) 355-7188

b. Update the research related injuries section.

Correct the information regarding responsibility for research related injuries (found in the "**What happens if I am injured or sick because I took part in this research study?**") so that it resembles the current model consent posted on the OPRS website. (See page 12 of the model consent form)

[Include only what applies to the study.]

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

Providing your care does not mean that DF/HCC or the research doctors are at fault, or that there was wrongdoing. There are no plans for DF/HCC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

--- OR ---

[If there is sponsor-specific injury language, add it here.]

c. Update the HIPAA section.

Please revise the "**Why will protected information about me be used or shared with others?**" section (HIPAA) so that it coincides with the model consent posted on the OPRS website. The following language should be replaced if included:

Please DELETE:

"(You will also be given the DF/HCC notice for Use and Sharing of Protected Health Information, which provides more information about how DF/HCC and its affiliates use and share protected health information.)"

Please REPLACE WITH:

"(You will also be given a notice for use and sharing of protected health information.)"

d. Update the signature pages for consent and assent.

New signature requirements for consent and assent: Please update the Documentation of Consent page so that it coincides with the model consent currently posted on the OPRS website. The link below is for the OPRS website. Once you get to our site, click on investigator resources and then click on model consent (biomedical). You can copy and paste the documentation of consent page into your consent. If this is an adult only study, please delete the documentation of assent and for minor subjects sections. (See the last pages of the model consent form). Also, please delete any of the financial conflicts of interest verifications (this information is already captured in the protocol application).

3. UPDATED CTSU LETTER AND LETTER FROM OPRS FOR SPONSORS:

[Click to view the CTSU IRB Certification Letter for DF/HCC](#)

[Click to Open Letter from OPRS for Sponsors Outlining DF/HCC IRB Procedures](#)

4. *New Titles and New OPRS Staff Members:*

Please note:

IRB Coordinators are now known within the OPRS as Human Research Coordinators

Please help us welcome the following new staff members to the OPRS:

Emily Drowne - Regulatory Affairs Specialist

Nicole Brooks - Human Research Coordinator, Post Activation Group

Desiree de la Torre - Human Research Coordinator, Post Activation Group

Terri Greene - Human Research Coordinator, Pre Activation Group (biomedical studies)

Please note the following individuals will be moving into the following functional areas:

Yvette Monroe - Human Research Coordinator moving to Pre-Activation

Sara Harnish - Moving within Pre-Activation Group to focus on Non-Biomedical studies

[Click here for the current list of ORPS Staff which is posted on the OPRS website.](#)

Thank you!

For further information, contact:

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