



OPRS NEWS

The following news update from OPRS highlights various issues relating to protocol submissions and post-approval protocol events.

New Submissions

- (1) As of June 1, 2006, OPRS will be requiring a *short summary of the protocol* provided on the disk along with the consent form, for all new protocol submissions. The protocol summary should be one to two paragraphs in length.
- (2) In the protocol application, please remember that the protocol summary must be in language understandable to IRB members who are not physicians.
- (3) In the protocol application, OPRS reminds investigators to be specific as to recruitment methods. Any intention to use medical records, for example, as a form of recruitment must be noted in question 2 of the OPRS protocol application.
- (4) Continuing Education Dates: When submitting signature pages for the Principal Investigators and Research Study Teams, please make sure that the information regarding human subject education is up to date. If the forms do not reflect your most recent education completion date, it may hold up activation of the protocol. Please contact CTEO@dfci.harvard.edu if you have any questions about the DF/HCC continuing education requirements.

Amendments and Continuing Reviews

- (1) Protocol Revisions: For any protocol revision, please be sure to resubmit the most current appendices that are listed in the protocol table of contents.
- (2) Consent Revisions: When submitting revised consent forms as part of an amendment (or continuing review) submission, please also incorporate the following important changes from the recent informed consent template:
 - (a) updated financial services phone numbers;
 - (b) correct 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?";
 - (c) new signature requirements for consent and assent;
 - (d) deletion of the financial conflicts of interest verifications (this information is already captured in the protocol application and will be managed on a case by case basis).

(3) General Revisions : When submitting revisions, please track your changes using the "tracked-changes" function rather than using the highlighting function. This will assist us in preparing copies for the reviewers that are legible.

Post-approval Events

OPRS received over 1800 deviations, violations and exceptions in 2005. Please note that the corrective action plan in the report must be meaningful and substantive or the report will be returned and deemed incomplete.

OPRS Information Sheets

Please check the OPRS website for regular updates and note our new evolving library of OPRS information sheets on such topics as Single Patient INDs; Linked and Anonymous Specimens; Medical Devices; and Research Use of Stored Data and Tissues.

Thank you!

For further information, contact:

The Office for the Protection of Research Subjects
20 Overland Street
2nd Floor
Boston, MA 02115
617-632-3029