



OPRS NEWS

**This OPRS News Item Is Directed To Principal Investigators And
Study Staff Of Protocols That Involve Tissue Collection.**

**OPRS NEWS ALERT
8-24-2006**

Tissue collection protocols

On June 30, 2006, OPRS distributed and posted on the website an OPRS info sheet for "instructions on the collection and sharing of data and tissue specimens.

To assist OPRS in processing these types of protocols and avoid lapses in IRB approval, please do the following:

1. Review the OPRS information sheet available at: www.dfhcc.harvard.edu/fileadmin/dfhcc_admin/clinical_trials/oprs/uploads/investigator_resources/oprs_info_sheet_-_collecting_sharing_data_and_tissue_specimens.Pdf
2. Review your current tissue collection protocol, informed consent document and supporting documents to determine whether they are consistent with these guidelines.
3. If necessary, submit the revised protocol, informed consent document and/or supporting documents to OPRS as follows:
 - A. If a continuing review report has already been submitted and approval is still pending, please contact Sara Harnish, JD at 617-632-5457.
 - B. If the protocol is set to expire within the next 90 days, please submit the revised protocol, informed consent and supporting documents with your continuing review report and include a description of the changes.
 - C. If scenarios (a) and (b) above do not apply, please submit the revisions as an amendment to OPRS ASAP.

Protocols involving the collection of bone marrow and extra tissue (excluding blood) for research purposes.

Please note that protocols involving the collection of bone marrow and extra tissue for research will be forwarded to the fully convened IRB for review. Accordingly, we request that the continuing review reports for such protocols be submitted at least 60 days before the expiration date so that we can schedule the protocol for a timely review. Please note that some protocols may be put on hold until the protocol is reviewed by full board. Please contact Sara Harnish, JD at OPRS with any questions.

Thank you!

For further information, contact:
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617-632-3029