



OPRS NEWS

Revised Forms and New Information Sheets Available

OPRS NEWS ALERT **4-30-07**

1. New and Revised Application Forms. Please be advised that the following revised or newly created forms have been posted to the OPRS website. We ask that all submissions to our office be submitted using the most current versions of the applicable form. Beginning May 15, 2007, submissions may be returned and not processed if they are submitted on older versions.

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

- **Radiation Safety Screening Form:** This is a new form designed to facilitate Radiation Safety Review. Please note that the questions related to the use of ionizing radiation have been removed from the main application form. Study teams must submit this screening form with all New Project Applications for Clinical Trials.
- **New Project Application - Clinical Trials:** This form has been significantly revised. The most significant changes are as follows:
 - a. General formatting.
 - b. Data and Safety Monitoring section (see question 5).
 - c. Need for IND and status of IND application submission (see questions 27-28)
 - d. Submission Checklist (see Part F - last page) -- Please note that OPRS is now requesting electronic copies of certain study documents including the Radiation Screening Form.
- **New Project Application - Social and Behavioral:** This form has been revised. The most significant changes include:
 - a. Requesting information regarding the setting in which the research will take place (question 1)
 - b. Updated links to guidance (question 7)
 - c. Requesting plan to protect subject information (question 10)
 - d. Added additional funding questions (question 14)
 - e. Added additional site utilization questions. (question 15 et. seq.)
- **New Project Application - Medical Record Review:** This form has been revised. The most significant changes include:
 - a. Requesting plan to protect subject information (question 9)
 - b. Updated links to guidance (question 11)
 - c. Added additional funding questions (question 12)

- d. Added additional site utilization questions. (question 13 et seq)
 - e. Submission Checklist (last page)
- **New Project Application - Use of Human Tissue and Specimens:** This form has been revised. The most significant changes include:
 - a. Requesting plan to protect subject information (question 9)
 - b. Updated links to guidance (question 13)
 - c. Added additional funding questions (question 14)
 - d. Added additional site utilization questions. (question 15 et seq)
 - e. Submission Checklist (last page)
- **Request for Exemption or Determination that Activity Is Not Human Subject Research:** This form has been significantly revised. The changes include:
 - a. General reformatting
 - b. Now can be used to request a determination that the project/activity is not human subject research. This is most helpful when sponsors request study teams to provide documentation that an independent determination was made that the activity does not involve research or does not involve human subjects as defined by the Federal regulations (e.g. certain uses of human specimens).
- **Continuing Review Form:** This form has been revised. The changes include updating questions related to progress to date (question 6).

2. New OPRS Information Sheets Available. Please note that the following information sheets have been posted for your reference:

- **Information Sheet: Determining if Project is Human Subjects Research.**
- **Information Sheet: Common Issues in Protocol Reviews.** This information sheet is intended to provide study teams with a list of issues that hold up the protocol review process. Many of them are related to the correct completion of forms. As additional issues become apparent, we will incorporate them into the list.

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

Thank you!

For further information, contact:
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