

## Office for Human Research Studies

### *Updated Policies & Procedures for the Endorsement of New Research Protocols*

Please be advised that the policies and procedures for the **Endorsement of New Research Protocols** submitted to OHRS for review by the SRC and IRB have been updated. New forms and guidance documents have been posted to the OHRS website.

- **Endorsement Form.**

The new Endorsement Form will replace the endorsement letter to ensure greater consistency and completeness. The form requests information that must be addressed by the Scientific Review Committee and must be submitted with all clinical and non-clinical research that is not exempt under the human subject protection guidelines.

**Please note:** The current version of the Endorsement Form is dated 1/27/2009. After 3/1/2009, new non-exempt human research projects submitted without an Endorsement Form will not be accepted by OHRS. The form can be found at <http://www.dfhcc.harvard.edu/ohrs> under "Submitting a New Protocol".

- **Guidance on Completing Endorsement Forms.**

OHRS has created this guidance document to assist study teams identify from whom they should request an Endorsement Form. Please note that the requirement for Endorsement Form now extends to some non-clinical research as well as clinical trials.

**Please note:** The guidance document can be found at <http://www.dfhcc.harvard.edu/ohrs> under "Submitting a New Protocol" and "OHRS Information Sheets".

- **Program Leader List for Signing Endorsement Forms.**

This list includes designated signatories for the endorsement forms for disease and discipline-based programs. It also includes signatories for research that does not fall into designated programs such as transplant, non-malignant hematology and non-malignant HIV related studies, etc. This list will be updated as additional individuals who may sign endorsement forms are identified.

**Please note:** The list can be found at :  
[https://www.dfhcc.harvard.edu/membership/login/?return\\_url=&pageId=1180](https://www.dfhcc.harvard.edu/membership/login/?return_url=&pageId=1180)

Please do not hesitate to contact OHRS if you have any questions or require additional

information.

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(Please note: OPRS is now the Office for Human Research Studies.)

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