

Guidance on Completing Endorsement Forms

In September of 2006, the DF/HCC instituted a requirement that all human research protocols submitted to the Scientific Review Committee for review pursuant to the Cancer Center Support Grant be accompanied by an endorsement from the Program Leader or Clinical Trials Chair for the relevant Disease or Discipline-Based Program. This process was instituted to aid in fulfilling the NCI requirement that before approving a trial, cancer centers assess the scientific merit, weigh the priority of the proposed clinical trial in light of the existing portfolio of approved trials, and affirm the potential to meet the accrual goals. The endorsement form also provides assurance that the proposed research fits within the mission and focuses of the Disease or Discipline-Based Program, and is supported by programmatic and clinical trials leadership within the research program.

This document provides guidance regarding protocol endorsement.

Every protocol submission must include an endorsement form, except as outlined below. The form is posted on the OHRS website: <http://www.dfhcc.harvard.edu/ohrs>.

How do I determine the right person from whom to request endorsement?

A list of Disease or Discipline-Based Program Leaders and Clinical Trial Chairs is posted on the CRU portion of the DF/HCC website. This list includes signatories for nursing initiated/focused studies. If you still have a question after reviewing this list, please contact Michele Russell-Einhorn at 617-632-3032 or Michele_Russell-Einhorn@dfci.harvard.edu.

What about pediatric oncology trials?

- For pediatric oncology trials, the process is as follows:
 - When the pediatric research protocol is submitted to OHRS for scientific review, the investigator will be required to submit a draft endorsement form but no disease program leader signature is required at that time.
 - The endorsement form will be completed by the Pediatric Scientific Review Committee (PSRC) after its review of the proposed research.
 - A copy of the PSRC's endorsement form will be sent to the program leader (s) of the relevant Disease or Discipline-Based Program to confirm that the trial is of high importance, has appropriate prioritization, and feasibility of realizing accrual. This will keep the Disease or Discipline-Based Program Leader informed, while providing a level of expert review of pediatric trials that was not available through the prior mechanism.
- Trials that include both pediatric and adult populations will need an endorsement form from the relevant Program Leader for the adult component before being submitted to OHRS. The pediatric review and endorsement form will come from PSRC following PSRC review.

- A pediatric trial will not be forwarded to the IRB for review until there is both scientific review approval from PSRC and a finalized endorsement form.

What about a discipline based trial?

For those protocols that are discipline based, but propose to enroll subjects from one or more disease programs, it is critical that the disease program leaders are aware of and support the discipline based trial. The investigator of the discipline based protocol is responsible for obtaining concurrence from the disease program leaders. There is a question on the endorsement form that asks this question.

What if the overall investigator is the same person as the program leader?

If the Program Leader is also the overall principal investigator, one of the other leaders for that program, who is not an investigator on the study, should sign the endorsement form. In the event that there are three program leaders and one is the overall principal investigator and the other two are site responsible investigators, either of the site responsible investigators may sign the endorsement form.

What if the proposed research spans more than one program?

If the proposed research is relevant to more than one disease program, the endorsement form should be prepared by the program leader for the disease site that is likely to accrue the most subjects. The investigator is responsible for obtaining concurrence from the other disease program leaders from which subjects will be accrued. This is to ensure that the research is in line with the mission and objectives of all involved disease programs. There is a question on the endorsement form that asks for this information.

For research that is relevant to both a disease and discipline based program, the endorsement form should be prepared by the program leader for the applicable disease program. The discipline based program leader should prepare the endorsement form if the research is non-disease specific.

What if my research does not fall into any of the DF/HCC designated disease or discipline based programs?

We recognize that in limited situations, research reviewed by the DF/HCC SRC may not fall into one of the formally designated disease or discipline-based programs (for example, research in non-malignant hematology). In anticipation of such circumstances, individuals have been identified to sign endorsement forms for research areas that frequently fall outside these programs. They have been included in the list of individuals eligible to sign endorsement forms that is available from the CRU portion of the DF/HCC website.

1. Studies that are not cancer-related and do not involve cancer patients (e.g. non-malignant hematology) do not require an endorsement form and do not need to be reviewed by the SRC.
2. Studies that are not cancer focused but involve cancer patients (e.g. anti-fungal studies, AIDS/HIV studies that draw from both cancer and non-cancer patients) do not require an endorsement form and do not need to be reviewed by the SRC.

What if my research is not cancer related?

Research that does not involve any cancer patients does not require the submission of an endorsement form. Additionally, upon confirmation by OHRS that the research is not cancer related, no SRC review will be required. The following list is provided as a guide as to what is and is not considered cancer-related:

Cancer Related:

Neurofibromatosis
Langerhans Cell Histiocytosis (LCH)
Myelodysplastic Syndromes (MDS)
Myeloproliferative Disorders

Not Cancer Related:

Thrombotic Thrombocytopenic Purpura (TTP)
Idiopathic Thrombocytopenic Purpura (ITP)
Fanconi Anemia
Diamond Blackfan Anemia (DBA)
Anemia
Gaucher Disease
Meningitis
Healthy populations
Sickle Cell
Hemophilia
HIV (unless cancer specific – i.e. Kaposis)
Scleroderma
Deep Venous Thrombosis
Cervical Dysplasia

Does this endorsement policy apply to non-clinical research, including research that is minimal risk?

Yes, in some cases.

- **Medical Record Review.** Protocols submitted on the Medical Record review application form will not require an endorsement form.
- **Social & Behavioral Research.** Protocols submitted on the Social & Behavioral application form that involve a prospective intervention or focus group will require an endorsement form *without the signature of a biostatistician*.
- **Use of Already Existing Specimens.** Protocols submitted on the Use of Human Specimens application form, which involve only the use of already existing specimens, will not require an endorsement form.
- **Use of Human Specimens (prospective collection).** Protocols submitted on the Use of Human Specimens application form, which involve the use of specimens that do not already exist at the time the protocol is submitted to OHRS, will require an endorsement form *without the signature of a biostatistician*.

What if I have more questions?

We realize that you may have questions about the process or there may be some trials that are not fully addressed by these general policies.

If you have questions, please contact Michele Russell-Einhorn, Senior Director of OHRS, at 617-632-3032.