DFCI IRB APPROVED STANDARD DRUG RISK LANGUAGE

The Dana-Farber Cancer Institute (DFCI) Institutional Review Board (IRB) approves standard drug risk language for inclusion in consent forms. DFCI IRB-approved language is published in the Standard Risk Language Library for use by the DF/HCC research community.

The Library is available on the OHRS website and may be accessed here.

I. DFCI IRB Review Process for Standard Drug Risk Language

OHRS drafts standard drug risk language by compiling and verifying information from the following resources:

- National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP): Tables of Possible Side Effects for Commonly-Used Oncology Drugs
- Partners Healthcare MicroMedex Solutions and MicroMedex CareNotes
- Consent forms from recently DFCI IRB approved protocols

Drafts are then finalized and approved by a DFCI IRB member who is a medical oncologist. Once approved, the language is added to the Library on the OHRS website including a DFCI IRB Approved Version Date.

II. Using the Standard Drug Risk Language Library

When standard risk language for a given drug is available in the Library, study teams are encouraged to include it in the consent form. Doing so ensures that clear and accurate information is presented to participants and prevents delays during DFCI IRB review.

The standard risk language is formatted in such a way that study teams can copy and paste it into the consent form template. Study teams are responsible for making revisions as appropriate for the specific study and participant population. While the DFCI IRB will generally accept the standard drug risk language if included in the consent form, revisions may be required for study-specific reasons.

Please refer to the Library regularly for updates as frequent revisions and drug additions are anticipated. When revisions are approved by the IRB, the DFCI IRB Approved Version Date will be updated.

III. Requesting Updates to the Standard Drug Risk Language Library

If you would like to suggest revisions to the current language published in the Library please email OHRS at ohrs@dfci.harvard.edu and put “Standard Drug Risk Language” in the subject line. Please

include the proposed revised risk language, as well as the rationale and source for the proposal. The proposed revisions will be reviewed by the IRB as outlined above.

IV. Requesting New Risk Language for Drugs Not Included in the Library

Please contact OHRS if you would like to request that new standard risk language be approved by the DFCI IRB and published in the Library. Please note that standard language will only be published for FDA-approved drugs. This is because the risk profiles for unapproved drugs change frequently.

If your study involves a drug for which standard risk language has not been published, you may contact OHRS for language that has been approved by the DFCI IRB in the past for other studies. If available, OHRS will provide this language for reference. However, as it has not been approved by the DFCI IRB for use as standard language, the study team is responsible for ensuring that it is accurate and appropriate, and the DFCI IRB may require revisions.

For questions, please contact OHRS at (617) 632-3029 or ohrs@dfci.harvard.edu.