National Cancer Institute (NCI)
Experimental Therapeutics Clinical Trials Network (ETCTN) Guidance

Local Consent Development

Contents

Introduction

After retrieving the NCI Central Institutional Review Board (CIRB) approved documents from the NCI Cancer Trials Support Unit (CTSU) website, the lead DF/HCC investigator is responsible for creating the local DF/HCC consent. The NCI CIRB Local Context Boilerplate Consent Language on the DF/HCC website must be used to create this document.

Subjects consented at DF/HCC will only use the local consent form.

Procedure

1) Collect the NCI CIRB approved model consent from the CTSU website and the CIRB Consent template from the DF/HCC website.
2) Transfer the language from the NCI CIRB approved model consent into the DF/HCC CIRB consent template.
   a) It is important to transfer exact language from the NCI CIRB approved model consent into the DF/HCC CIRB consent template. No modifications to the consent language can be made at this point.
3) Submit both the NCI CIRB model consent and the local DF/HCC consent to OHRS along with the CIRB New Project Application.

Links

CTSU Website Login: https://www.ctsu.org/public/default_login.aspx

DF/HCC CIRB Consent Template: http://www.dfhcc.harvard.edu/index.php?id=973#ncicirb