

# Amendments to OHRS

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## Introduction

Per National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) policy, all ETCTN protocol amendments must be activated locally within 30 days of the amendment notification being posted on the CTSU website. The lead DF/HCC study team should submit protocol amendments to the DF/HCC Office for Human Research Studies (OHRS) as quickly as possible and respond to follow up requests in a timely manner to ensure the 30-day implementation requirement is met.

## Procedure

1. The DFCI ETCTN contact will retrieve the amendment documents from the CTSU Members’ Website and provide a copy to the study team and to potential amendment reviewers as described on the DF/HCC website: <http://www.dfhcc.harvard.edu/news/detail/story/nci-ctep-30-day-amendment-activation-requirement/>.
2. The lead DF/HCC study team will retrieve the [OHRS Single IRB Amendment form](#) from the OHRS website.
3. The lead DF/HCC study team will complete the Amendment Form and update all applicable documents.
4. The lead DF/HCC study team will submit the Amendment Form and applicable documents via OHRS Submit as soon as possible to allow adequate time for processing and activation prior to the 30-day deadline.
5. OHRS will process the submission and route to the Activation Agents in P360 as High Priority
6. OHRS will post the updated documents to OncPro for study team use.

## Links

CTSU Member Website: <https://www.ctsu.org/Public/Default.aspx>

DF/HCC Notice Regarding NCI CTEP 30 Day Amendment Activation Requirement:  
<http://www.dfhcc.harvard.edu/news/detail/story/nci-ctep-30-day-amendment-activation-requirement/>