Manual for the Completion of the NCI / CCR / C3D Case Report Forms

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Disclaimer: This manual was developed by Harris IT Services for the National Cancer Institute's Center for Cancer Research (CCR). The material contained in it is solely for assisting data entry into CCR's Cancer Central Clinical Database (C3D) electronic case report forms.

Introduction

At the end of 2003, the National Cancer Institute's Center for Cancer Research (CCR) developed and started using the Cancer Central Clinical Database (C3D) - a client-server computer system - to capture data for oncology clinical trials research trials conducted at the CCR.

This manual contains the instructions for the completion of the NCI's standard Case Report Forms used in C3D.

The eCRF instruction manual is preceded by a General Instructions section which describes topics applicable to all eCRFs. This is followed by instructions for each form which include how to complete each field, what the validation rules are for the CRF, and what fields will be derived by the database. The Appendices include conversion tables and useful Internet and Intranet references and standard lab panels.

For BTTC Studies, refer to the BTTC eCRFs Instructions Manual.

Changes to Case Report Forms since Last Version of the Manual

Previous Versions of the eCRFs Instructions Manual

2013 Version in a single PDF (outdated). (No large CRF screenshots!)
# Case Report Forms Instructions

## General Instructions

- [x] General Instructions
- [x] Adverse Events
- [x] Baseline Medical History
- [x] Baseline Symptoms
- [x] Cardiac
- [x] Chimerism
- [x] Concomitant Measures and Medications
- [x] Course Assessment
- [x] Course Initiation
- [x] Consults (new)
- [x] ECG
- [x] Eligibility Checklist
- [x] Enrollment
- [x] Extent of Disease
- [x] Extent of Disease (Neuro Oncology Branch) (new)
- [x] Follow up
- [x] Infection Episode
- [x] Labs
- [x] Medical Record Numbers
- [x] Off Study
- [x] Off Treatment
- [x] Pathology Report (new)
- [x] Pharmacokinetics
- [x] Physical Exams - Screening
- [x] Physical Exams - Courses
- [x] Prior Radiation Supplement
- [x] Prior Surgery Supplement
- [x] Prior Therapy Supplement
- [x] Prior Treatment Summary
- [x] Procedures
- [x] Radiation
- [x] Study Medication Administration
- [x] Storage (new)
- [x] Surgery
- [x] Survival
- [x] Transfusions
- [x] Urinary Excretions
- [x] Vital Signs

## Appendices

- Appendix I - Conversion Tables
- Appendix II - Useful References
- Appendix III - Lab Panels
- Appendix IV – Lab Load Interface (LLI) Tool
## Case Report Forms for GVHD Studies

### Under Development
- cGVHD - Activity Assessment Clinician
- cGVHD - Activity Assessment Patient Self Reported
- cGVHD - Characteristics at Enrollment
- cGVHD - Composite Assessment Scale
- cGVHD - Composite Assessment Scale (Continuation)
- cGVHD - Patient Symptom Scale
- cGVHD - Qualitative Research Questions
- cGVHD - Treatment History

## Changes to Case Report Forms since Last Version of the Manual

### New Standard eCRFs
- Consults
- Extent of Disease (Neuro Oncology Branch)
- Pathology Report
- Storage

### Updated eCRFs

#### Adverse Events
- Serious instructions clarified.
- Added Expedited to Manufacturer.

#### Chimerism
- Specimen picklist updated.

#### Enrollment
- Gender picklist updated.
- Disease Term picklist using CTEP Simplified Disease Code list.

#### Extent of Disease
- eCRF broken into two: one for the Lesion Identifications and another for the Lesion Measurements.

#### Labs
- Added 2 new eCRF Lab Panels: HLA and Chimerism.

#### Off Study
- Removed Reason 'O' from Off study Reason Picklist used in studies that have Follow-up period.