

**University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center
Study Management Guidance**

**Guidance for Completion of Baseline Condition CRFs for Patients on
Investigator-Initiated Therapeutic Oncology Clinical Trials**

Purpose

This policy defines the mandatory capture of baseline conditions for Case Report Form (CRF) completion and describes what is considered a “baseline condition” for the purpose of clinical data for investigator-initiated therapeutic trials at the Helen Diller Family Comprehensive Cancer Center (HDFCCC). This policy applies to all therapeutic trials that are investigator-sponsored with CRFs in OnCore® Clinical Trial Management System.

Background

Knowing the baseline characteristics of the trial participants allows investigators to assess how closely these match other participants, and therefore how generalizable the results of the trial will be. Baseline data are measured as close as possible to the time that participants are randomly allocated to study groups, and in all cases, should be measured before the allocated treatment commences (information collected after the commencement of trial treatment may have been altered by the treatment itself, and is generally not regarded as baseline data). Ideally, baseline data should be collected on all patients screened for eligibility, as this would provide further information about the generalizability of the trial population.

At the beginning of a subject's screening visit, the provider will summarize the current state of health for the matter of what is considered “baseline”. In Industry sponsored studies, the data for this is often captured on several forms, labeled as Medical History or Surgical History, which include: 1) stratification factors, 2) factors that alter the outcome, and 3) factors that predict or alter adverse events. The OnCore CRF has chosen the term “Baseline Condition” to consolidate those clinical events that can be graded to provide a baseline focusing on future adverse events, but also entered are conditions that can also help the investigator in the other two factors when analysis is completed.

References

- *ICH Guidance for Industry: Structure and Content of Clinical Study Reports, July 1996.*
- *FDA Guidance for Industry: Cancer Drug and Biological Products, Clinical Data in Marketing Applications, October 2001.*
- 42CFR410.16

Procedures

1) *Responsibilities of the physician investigator (MD) or Nurse Practitioner (NP) or qualified research nurse (RN or CNS) or other clinical providers include documenting:*

- All active medical conditions without an end date
- All surgeries related to current conditions and eligibility
- All medical conditions that have concomitant medications

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- Screening tests that identify a new baseline condition (i.e. thyroid lab tests resulting in Hashimoto's disease).
- All clinically significant abnormal labs at screening (list the medical condition/diagnosis related to this lab result first, and if none, then the lab itself). (An example of this would be anemia from grade 1 hemoglobin results).

2) Responsibilities of the Clinical Research Coordinator include capturing from the UCSF provider on the Baseline Condition CRF, any subject history obtained from outside providers in the course of screening:

- All active medical conditions without an end date
- All surgeries related to current conditions and eligibility
- All medical conditions that have concomitant medications
- All clinically significant abnormal labs at screening (list the medical condition/diagnosis related to this lab result first and if none, then the abnormal lab)
- All events should have a start date which may require contacting the subject to help identify an accurate start date.

Alternate Procedures

There are no alternate procedures to the HDFCCC policy of key personnel who can obtain consent.


Policy Review

Review and revision to this policy to be completed once per year.


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Policy Approval

This policy document was approved by the following personnel on the following dates:



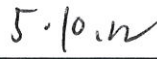
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Date



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Date



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Date

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Attachment 1 (Case Examples of baseline condition problems found in monitoring)

1. Recording past medical history, but leaving out all past surgical history including documentation of hysterectomy/ovaries removed (helpful for eligibility documentation for females).
Both active medical and surgical history should be included in the OnCore baseline eCRF.
2. If subject has abnormal labs pre-study (baseline), the abnormal labs are not included for various reasons given:
 - a) Grade 1 or 2 lab AEs are not captured for this study in OnCore (i.e. Phase 2 studies).
 - b) PI documents all pre-study labs as NCS, thus all labs in general will not be entered as baseline conditions.***Baseline laboratory results that are abnormal (whether or not documented as CS or NCS) should be added to the OnCore baseline eCRF if the labs will be significant in determining eligibility or dose modifications.***
3. Subjects are on routine medications for hypertension and hypothyroidism, but these conditions are not listed as baseline conditions.
Even if the PI is not capturing all concomitant medications, the reason for medications taken by the study subject should be added to the OnCore baseline eCRF.
4. Documents only those baseline conditions that are relevant to the diagnosis. Examples are urinary symptoms in prostate cancer patients and are identified by the PI to be collected.
Abstracted baseline conditions should be all relevant medical, surgical, and laboratory abnormal values to adequately serve as a baseline prior to adverse event documentation.
6. Some studies are only interested in capturing active medical conditions and these active medical conditions are often collected without a start date.
OnCore baseline condition documentation should include both active and not active conditions that are relevant to eligibility and if necessary the CRC should request needed documentation to determine start date.
7. Some baseline conditions may be intermittent and thus not active at the time of screening. (e.g., a patient has intermittent grade 1 nausea that is not active at screening, but then after treatment, the patient suffers grade 1 nausea).
Any baseline condition that is discovered later during treatment should be documented and added to the baseline log, with appropriate grade and followed until the grade increases or stops.