

OHRS Information Sheet

Common Language for Risks and Events Database

The compiled list of Common Language for Risks and Events comes from primarily three sources:

1. Dana-Farber Cancer Institute (DFCI) Institutional Review Board (IRB) meetings
2. Common Toxicity Criteria for Adverse Events v3.0 (CTCAE)
 - a. http://ctep.cancer.gov/reporting/ctc_v30.html
3. Stanford Online Glossary
 - a. <http://humansubjects.stanford.edu/general/glossary.html>

This Info Sheet is designed to generally describe the OHRS Common Language for Risks and Events and how to use this database.

Considerations for use:

The Common Language for Risks and Events Database is available to the DF/HCC research community as searchable database. Each LayTerm should be used as a guide, and only a guide, to describe risks to participants within a consent form document. The IRB may require revisions to any proposed language originating from this database within the context of a study or require additional information beyond the language provided in this resource. For example, expanding upon the stated LayTerm to include what the LayTerm will mean to participants if it should occur, often including severity (e.g. "...which may be serious or life-threatening"), reversibility and frequency.

This is an evolving database and frequent revisions are expected. Please refer to this database often for updates. When appropriate the revisions proposed by IRB that are considered to be common, or "standard language", will be incorporated into the Common Language for Risks and Events Database and the RevisedBy and RevisedDate will be updated by the OHRS. With that in mind, there are some cases where a duplicate Term and associated LayTerm maybe included in the database. Please note the Source of the differing LayTerm's provided and use your best judgment to include the appropriate language within your consent form document until such a time as the IRB reviews and revises the language into one commonly used LayTerm.

If while drafting your consent form document you have any suggested revisions to the language provided in this database, including additions, the OHRS would like to hear from you. Please contact Emily Eldh in the OHRS via email at eeldh@partners.org including the proposed new or revised Category, Term, SubCategory, and LayTerm. If the language is from a source other than the individual providing the language, please include the Source as well. If the language is a result of a new DrugSpecific risk, please include the drug name and any associated information (e.g. Action Letter, etc.) for review by the IRB. Appropriate steps will be taken to review the proposed revisions and additions and if approved they will be included in a future update of the Common Language for Risks and Events database.

How is the Common Language for Risks and Events Organized?

This resource is organized into 11 headings and 25 Categories as listed below.

Headings (with definitions):

1. ID: Short 3-4 letter acronym for each Category
2. ID #: ID number associated with each individual Term within a Category.
3. Category: a grouping derived primarily from the CTCAE v3.0
4. Term: a word or words describing a type of risk or event derived primarily from the CTCAE v3.0
5. SubCategory: additional word or words describing more specifically a type of risk or event derived primarily from the CTCAE. Where no SubCategory applies the Term is repeated in SubCategory.
6. LayTerm: a common definition of the Term and SubCategory derived from one of the three sources noted above and may include revisions by the DFCI IRB and subsequently considered "standard language".
7. Source: states where the Term and LayTerm originated from.
8. Revised By: states which IRB panel or IRB member last reviewed and revised the LayTerm.
9. Revised Date: date the LayTerm was last revised.
10. Drug Specific: If the language originated from a specific adverse event associated with a specific drug, the drug is listed here and the language should be included in consent forms for studies using that drug.
11. Notes: section where any notes can be included by the OHRS or IRB to clarify the common language and its use or origin.

Categories

1. Allergy / Immunology (AI)
2. Auditory / Ear (AUD)
3. Blood / Bone Marrow (BBM)
4. Cardiac Arrhythmia (CA)
5. Cardiac General (CG)
6. Coagulation (COAG)
7. Constitutional Symptoms (CS)
8. Dermatology / Skin (DERM)
9. Drug Specific Language (DSL)
10. Endocrine (END)
11. Gastrointestinal (GI)
12. General Medical Term (GMT)
13. Hemorrhage / Bleeding (HEM)
14. Hepatobiliary / Pancreas (HEP)
15. Infection (INF)
16. Metabolic / Laboratory (LAB)
17. Lymphatics (LYM)
18. Musculoskeletal / Soft Tissue (MUS)
19. Neurology (NER)
20. Ocular / Visual (OCU)
21. Pulmonary / Upper Respiratory (PUL)
22. Renal / Genitourinary (REN)
23. Sexual / Reproductive (REP)
24. Syndromes (SYN)
25. Vascular (VAS)