

CNS-D-01 — UNIQUE IDENTIFIERS FOR HUMAN SPECIMENS

The SOP outlined here covers the processes for maintenance of subject confidentiality for biological specimens that are received by the CNL from human subject research studies. The procedures for samples received for routine clinical care are covered separately in the Institute-wide Quality Management Handbook.

Subject-specific unique identifiers

Biological specimens (blood, plasma, urine, tissue etc) from human subjects entered into clinical research studies originating from the CNL are encoded utilizing the unique identifiers designated for each human subject when first enrolled into the study (see SOP CNS-C-01). In situations in which samples are collected for both routine patient care and research purposes, specimens collected from patients may be labeled and processed according to the routinely followed procedures of the originating institution; however, for all such samples that are shipped to and/or stored at the LCN, as part of an IEC or IRB approved protocol, the labeling must include the unique identifiers designated for each human subject as they are entered into the study. Samples stored for purely research purposes in studies originating from the CNL are labeled only with the unique identifiers, as outlined in this SOP.

Specimen-specific tags

The particular specimen type for storage and/or analyses together with the nature of the particular sample or analyte(s) in a set of samples or analytes is tagged by an additional series of specimen identifiers. These additional sample tags vary according to the particular specimens to be analyzed or stored and procedures as stipulated in the clinical protocol. The complete series of identifiers with specimen tags for a specific study protocol are printed on specimen labels that are affixed to the sample collection vessels (e.g., 24 hr urine container), the specimen storage tubes and where appropriate the subject visit plan record (see examples on the following pages).

Dates & additional information

All sticky labels include a blank area that is filled with the date the sample was collected. Dates are entered as day, month, year (e.g., 01/01/10) using non-water soluble ink pen. The sticky labels also include information stipulating where each label should be affixed (collection vessel vs visit plan record or storage tube). Other information is also included about the specimen as it is collected according to the protocol (e.g., phase of study; baseline sample; standing sample).

Collection versus storage specimens

The coding of specimen-specific tags includes separate labels for both specimens collected (e.g., heparinized blood, 24 hr urines) and specimens further processed for storage (e.g., heparinized plasma, urine aliquots). Thus, additional information is included on sticky labels to distinguish collection samples from storage specimens. These labels may be provided in two pages (see example for PMT study), including a page for labels to be affixed to blood tubes, 24 hr urine containers and visit file records and another page for the samples stored for analyses or banking. In situations in which one sample type may be collected for multiple analyses or storage samples (e.g., 24 hour urine → multiple analyte-specific storage samples), the specimen-specific tag on the sticky label used for collection matches to only one of the specimen-specific tags for storage; nevertheless that collection sample may be used for multiple aliquots of storage samples with different specimen-specific tags.

Disposition of sticky labels

Sheets of sticky labels specific for each subject according to stipulated unique identifiers are stored with subject visit files that accompany subjects as they progress through the protocol-specified procedures. A sticky label is affixed to blood tubes as samples are collected or to the 24-hour urine containers that are provided to subjects for urine collections. Additional sticky labels to affix to specimen-storage tubes are maintained in the laboratory or may be peeled away from sheets, affixed to temporary backings (e.g., plastic sheets) and included with collection specimens for final affixing to sample storage tubes after blood specimens are centrifuged or 24-hour urine specimens processed before aliquoting of urine specimens into storage tubes.