

PMT3-C-1 — UNIQUE IDENTIFIERS FOR HUMAN SUBJECT RESEARCH

The SOP outlined here covers the processes for maintenance of subject confidentiality for biological specimens (blood, plasma, and urine) and data.

1. Patient data and specimens received and handled by the laboratory are for purely research purposes. They are encoded using unique identifiers and collected using clinical protocols approved by the appropriate Institutional Ethics Committee (IEC) or Institutional Review Board (IRB).
 2. This SOP outlines the system used to designate unique identifiers to human subjects enrolled into clinical research studies originating from the ENS@T.
 3. The unique identifiers for each human subject enrolled into research studies established by ENS@T are comprised of a combination of seven numeric and alphabetic characters (no spaces between characters). The first set of four alphabetic characters (1st- 4th characters in the series) refers to the study center where the subject is enrolled into the study. The first two characters in this series of four characters refer to a specific country code and the second set of two characters to a city or study center code specific to that country. The country codes are outlined in the document appended to this SOP. The city codes are specified by the identified central study center for each participating country. The final set of three digits in the series is unique to the particular subject enrolled into the specific study, which is established by a designated investigative team member at each participating center and at the time of subject consenting.
 4. Each patient is assigned a code automatically after written informed consent is obtained and registered to ENS@T. Samples cannot be collected until that patient is entered to ENS@T registration.
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System for Designation of Unique Identifiers to Individual Subjects		
Nation	Center	Subject No
Two alphabetic characters to designate the Nation for the Nation for the Center at which the subject is enrolled.	Two alphabetic characters to designate the Center at which the subject is enrolled	Three digits to designate the specific subject enrolled into the particular study.
e.g., for Germany GY	e.g., for Dresden DR	e.g., for 1st subject enrolled 001
Unique subject identifier in example above = GYDR001		
