

## CNS-C-01 — UNIQUE IDENTIFIERS FOR HUMAN SUBJECT RESEARCH

Data and biological specimens (blood, plasma, urine, tissue etc) from human subjects enter the Clinical Neurochemistry Laboratory (CNL) from two directions: 1. routine patient care; and 2. clinical research studies. The SOP outlined here covers the processes for maintenance of subject confidentiality for biological specimens and data that are received by the CNL from human subject research studies. The procedures for samples and data received for routine clinical care are covered separately in the Institute-wide Quality Management Handbook.

1. Patient data and specimens received and handled by the laboratory for purely research purposes are encoded using unique identifiers and collected using clinical protocols approved by the appropriate Institutional Ethics Committee (IEC) or Institutional Review Board (IRB). In circumstances where data and specimens are received for both patient care and research purposes, those data and specimens may be received with included identifying information (i.e., patient name).
2. This SOP outlines the system used to designate unique identifiers to human subjects enrolled into clinical research studies originating from the CNL. Other encoding methods are employed for studies originating from outside centers according to the established SOPs at those centers. Where such SOPs have not been established, the system outlined here may be adopted to designate unique identifiers for subjects for whom specimens and data are sent to the CNL under collaborative research studies, but only after prior arrangement with the Head of the CNL.
3. The unique identifiers for each human subject enrolled into research studies established by the CNL are comprised of a combination of nine numeric and alphabetic characters (no spaces between characters). The first character refers to the study number and the second alphabetic character to the subject group within the study, as may be required in studies involving different subject groups in which procedures under the protocol vary according to the group. The next set of four alphabetic characters (3<sup>rd</sup>- 6<sup>th</sup> 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, the latter reflected by the study number (i.e., the first character in the series of 9 characters). The last set of three digits is established by a designated investigative team member at each participating center and at the time of subject consenting.

### System for Designation of Unique Identifiers to Individual Subjects

Study number	Subject Group	Nation	Center	Subject No
Represented by a single numeric character unique to the particular study under which subjects are enrolled.	Specific character to specify the subject group within a study as may be required by that particular study.	Two alphabetic characters to designate 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 Study #1	e.g., for Volunteer	e.g., for Germany	e.g., for Dresden	e.g., for 1st subject enrolled
1	V	GY	DR	001
Unique subject identifier in example above = <b>1VGYDR001</b>				

**COUNTRY AND CENTER CODES FOR HUMAN SUBJECT UNIQUE IDENTIFIERS**

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**UNIQUE IDENTIFIER  
COUNTRY CODES**

<b>Nation</b>	<b>Nation Code</b>
Argentina	AR
Australia	AU
Belgium	BL
Brazil	BZ
Canada	CA
China	CH
Croatia	CR
Czech Republic	CZ
Denmark	DK
Finland	FN
France	FR
Great Britain	GB
Greece	GR
Germany	GY
Hungary	HY
India	IN
Ireland	IR
Israel	IS
Italy	IT
Japan	JP
Mexico	MX
Netherlands	NL
Norway	NY
New Zealand	NZ
Poland	PL
Portugal	PR
Russia	RS
South Africa	SA
Scotland	SC
Slovakia	SL
Spain	SP
Sweden	SW
Switzerland	SZ
Ukraine	UR
USA	US

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**UNIQUE IDENTIFIER  
GERMAN CITY CODES**

<b>Center/City</b>	<b>City Code</b>
Berlin	BN
Bautzen	BZ
Chemnitz	CZ
Düsseldorf	DF
Dresden	DR
Essen	ES
Frankfurt	FT
Freiberg (BB)	FR
Hamburg	HM
Hanover	HN
Halle	HL
Köln	KN
Leipzig	LP
Magdeburg	MD
Munich	MU
Nuremberg	NR
Regensberg	RG
Stuttgart	ST
Würzburg	WU

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