"G3P – Protection Practice in Clinical Research: Principles of Pseudonymization and Anonymization”

Karl-Heinz Schriever and Markus Schröder, 2014, 198 pages, De Gruyter, $196

Review by Norman M. Goldfarb

“G3P – Protection Practice in Clinical Research: Principles of Pseudonymization and Anonymization” presents the procedures and their rationales for privacy protection in clinical research and biobanks to comply with EU and U.S. (HIPAA Privacy) regulations. The book presents advanced material in a straightforward manner, although it would be easier to read if a native English speaker had been involved.

The following passage illustrates the detailed, step-by-step content of the book:

**Triple-coded Samples/Data**

Triple-coded samples/data are quite similar to double-coded samples/data described above (Fig. 45). Triple coded samples/data at the outset have a first random code (Patient ID) as identifier instead of the individual's name and a random barcode 1. A blood sample is identified by both identifiers. Only the investigator knows the identity (the name) of the individual to whom the respective code applies, and

- the investigator usually holds the key to the first code.

In a second step, the first code (Patient ID) and barcode 1 are registered prior to removing the Patient ID from the sample. Only barcode 1 remains on the sample. This can be done, e.g., by a central logistic CRO or by the staff of a biobank prior to storing the samples.

- The Patient ID and barcode 1 are held by a central, secured protection database.

In the third step, executed by a different staff with the logistic CRO, barcode 1 is replaced by a random barcode 2, the final identifier of samples and data.

- Barcode 2 is also held by a central, secured protection database.

The triple-coding process is called factual anonymization. It is more personnel-intensive than any other coding process but ensures a security-like anonymization with all the advantages of pseudonymization.

No one in the process chain gets any access to both identifiers (Patient ID and barcode 2), neither technically nor organizationally.

Neither the knowledge of the first or second code nor the knowledge of the third code is sufficient to trace back to the individuals identity. The knowledge of both codes and their mutual link are necessary to re-identify an individual (patient).

The book consists of 14 chapters and five appendices:

- Introduction
- Study Modes
- Protection Masks and Procedures
- Coding Methods for De-identified Samples/Data
- Relationships Among the Protection Masks
- Data Types
• Anonymization
• Validation – a Brief Introduction
• Request Management
• Legal Requirements & Regulations
• Informed Consent
• Selected Data Protection & Medical Sites
• Impact of External Services on Data Protection
• Practical Approach to Clinical Trials with Supplementary Genetic Parts
• Appendix 1: Data Protection in the European Union
• Appendix 2: Data Types
• Appendix 3: Protection Masks
• Appendix 4: Informed consent (IC)
• Appendix 5: Security

The book is available in bookstores.

**Reviewer**

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