Protecting Patients’ Rights in Medical Research Networks

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Integrate Health Care and Medical Research
To advance diagnostic and therapeutic knowledge.
Keep data and biomaterials for future research

Protect Patients’ Data and Biomaterials
According to rules of ethics and professional discretion as well as national and international data protection laws.

Separate Informational Powers
Data from analyses
Biomaterials, associated data
Images and associated data
Medical data
Identifying data

Additional safeguards compensate for
• vaguely specified purpose
• unlimited storage time

Pseudonymize Identifying Data
MDAT (encrypted)

Use distinct pseudonyms for MDAT, Biomaterials, Images

The TMF Concept
A “generic” model with variants for the processing of information in research networks and biobanks.
Methods: Separation of Informational Powers and Pseudonymization together with carefully formulated Informed Consent Templates and Standard Operating Procedures.
Several networks followed this approach. Others will follow. The German Data Protection Commissioners approved this concept.

The TMF Concept enables long time medical research data bases and biobanks, fulfils the privacy requirements, and gives freedom for medical research while protecting patients’ rights.

TMF, Telematikplattform für Medizinische Forschungsnetze e. V.