Electronic Consent for Hospital-Integrated Biobanks

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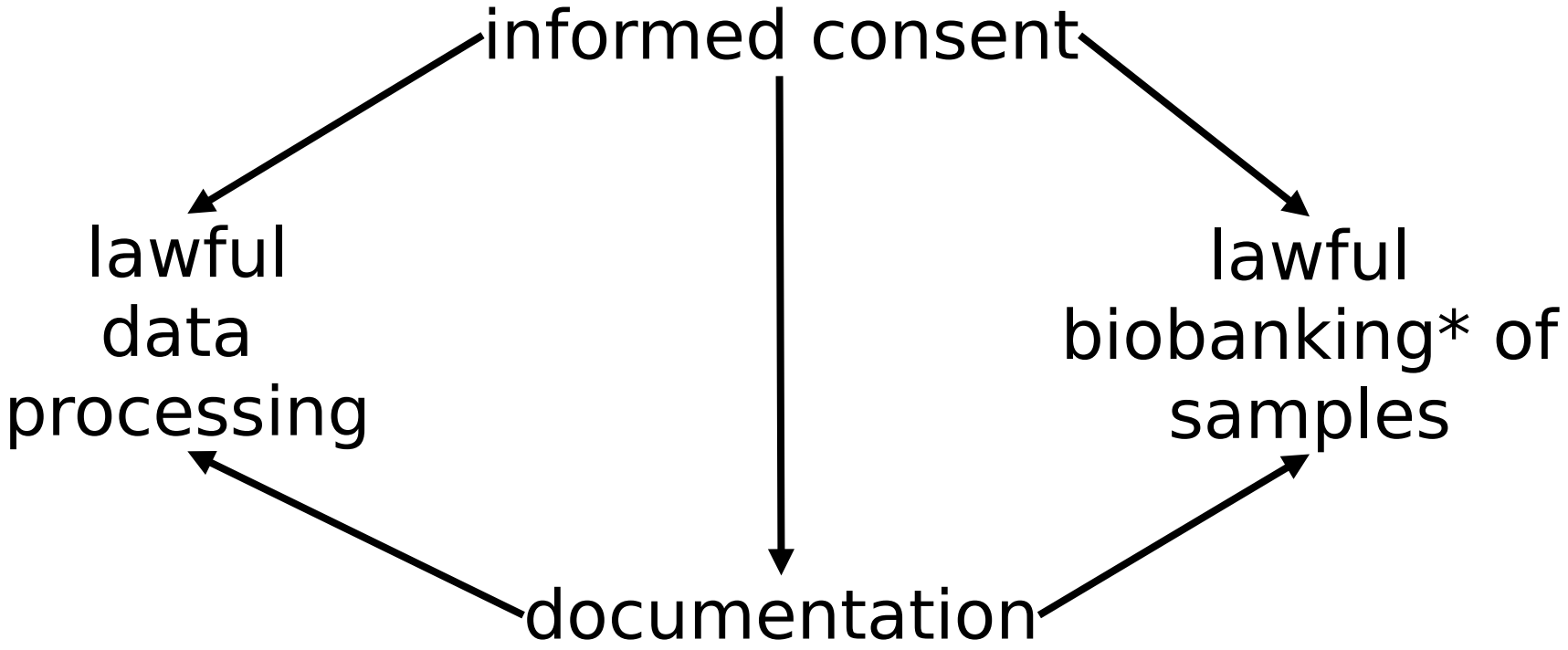
INTERDISCIPLINARY BANK OF BIOMATERIALS AND DATA WÜRZBURG ibdw

Consent from Biobank Perspective



* biobanking includes all sample related activities, such as collection, processing, storage or distribution

Current Workflow

- Informed consent during patient admission/patient briefing
- The signed consent form is stored in patient’s medical record (paper).
- Electronic documentation of consent by the briefing clinician in the hospital information system (HIS).
- A surgeon or ward physician reviews the consent status in the HIS and places the appropriate biobanking order.
- The consent status is obtained from the HIS for the biobank management system along with the patient pseudonym.

Uncertainties

- Is the informed consent at all valid?
  - Is the consent form filled out correctly?
  - Have all necessary options been addressed?
  - Has the form been signed by both, the patient and physician?
  - Was the patient eligible (age, capability)?
- Is the consent status properly documented in the HIS?
  - Is the status associated with the correct patient?
  - Is the consent status set correctly?
- Do we have a valid consent for the biosample?

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Tedious, complex, time-consuming and expensive process

The Better Solution

- Electronic consent
  - using an electronic consent form
  - only valid if completed
  - indicate missing information
  - immediate documentation in HIS
  - reliable and current information
  - fully traceable

Formal Consent Requirements

- law:
  - intervention=injury
  - property on detached body parts
  - personally identifiable information
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→ **GDPR**

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Requirements for Consent

- Conditions for consent (Recital 32)[4]
  - Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement.

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- Processing of special categories of personal data (Art. 9)[4]
  - [...] processing of genetic data, [... and] data concerning health [...] shall be prohibited.
  - Paragraph 1 shall not apply if one of the following applies:
  - the data subject has given explicit consent to the processing of those personal data for one or more specified purposes [...]

Explicit Consent

- Article 29 Working Party Guidelines on obtaining explicit consent[5]
  - Explicit consent is required in certain situations where serious data protection risk emerge, hence, where a high level of individual control over personal data is deemed appropriate.
  - It means that the data subject must give an express statement of consent.
    - expressly confirm consent in a written statement
    - it cannot be said that the GDPR prescribes written and signed statements in all circumstances that require valid explicit consent
    - a data subject may be able to issue the required statement by filling in an electronic form, by sending an email, by uploading a scanned document carrying the signature of the data subject, or by using an electronic signature.
    - In theory, the use of oral statements can also be sufficiently express to obtain valid explicit consent

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- Recital 42 Burden of proof and requirements for consent[4]
- EDPB Guidelines on Consent: Burden of proof[7]
  - The controller bears the burden of proof [..] for the lawfulness of the data processing and thus also the consent as a whole.
  - The controller should have enough data to show consent was obtained [..]
  - As long as a data processing activity in question lasts, the obligation to demonstrate consent exists.

Documented and Recorded Information

- Data controllers must be able to demonstrate, in relation to obtaining valid consent from data subjects:
  - How and when consent was obtained
  - What information was available to the data subject at the time of consent
  - That the workflow has met all relevant criteria for valid consent
  - A copy of the information presented to the data subject at that time
  - Measures for the retention and availability of the consent (at least as long as the data processing activity lasts)

Implementation

- eConsent® technology by Thieme was piloted
- The system is already used for patient information and consent to medical procedures
- Clinicians are already familiar with the procedure
- No additional hardware is required
- Mapping of the modular MII consent in the system
- Signature is captured along with characteristic information such as writing speed and pressure, making it compliant with advanced electronic signatures
- Consent document is stored along with the electronic signature and patient information
- Transfer of consent information to the biobank management system

Benefits

- Biobank
  - Consistent documentation and reliable and verifiable consent information
  - Easy adaptation to new requirements, e.g. for studies
  - Reliable consent statistics
  - Immediate update of consent status
- Clinician
  - Paperless consent process
  - No additional documentation required
- Patient
  - Presentation adapted to the patient's needs (e.g. language, disabilities)
  - Additional information channels for better understanding (e.g. videos, animations)
- Researcher
  - Immediate display of sample usability in terms of consent during sample queries

Constraints and Challenges

- Patients may feel uncomfortable, reluctant, or overwhelmed when asked to use an electronic device[8]
- High costs associated with devices and implementation efforts.
- Extensive and ongoing staff training requirements.
- Potential inconsistencies and errors when transitioning from or using alongside paper-based consent.
- Need for coordination with regulatory and supervisory authorities.
- Uncertainties about the validity and legal recognition of electronic consent, especially for cross-border sample use.

Summary

- Electronic Consent
  - is in line with applicable laws, regulations and guidelines
  - offers significant advantages in regard to reliability, traceability, verifiability and non-repudiation
  - improves the consenting process
  - enables reliable and complete documentation
- However, it may be advisable to provide paper consent for special cases.

Electronic informed consent: a further step towards optimizing workflows in the biobank!

Thank you for your attention

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