

Blockchain Uses for Dynamic Consent

Ethical Considerations for Data Management and Privacy

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What is Dynamic Consent?

- Approach to informed consent that enables ongoing engagement and communication among individuals and organizations
- Recognizes that individual autonomy changes
- *Primary goal:* Ongoing data sovereignty

Why is Dynamic Consent Important in Healthcare and Life Sciences?

There has been a shift to:

- Precision medicine
- Predictive analytics
- Real-world evidence
- Patient-centric design
- Internet of Medical Things



Examples of Dynamic Consent

- Share data with others
- Allow/decline data to be used for specific business purposes
- Enroll in new participatory programs or studies
- Choose how data or specimens are used for future research
- Several different consent choices
- Preferences for being contacted:
 - New options for participation
 - New risks or benefits identified
 - How data are being used
 - Learn outcomes of research

Role of Blockchain Technology

Individual-centric technology:

- Smart contracts provide automation
- Allows complex data ownership
- Allows granular consent
- Creates audit trails
- Offers transparency of use
- Enhanced security with encryption



Ethics of Blockchain Dynamic Consent

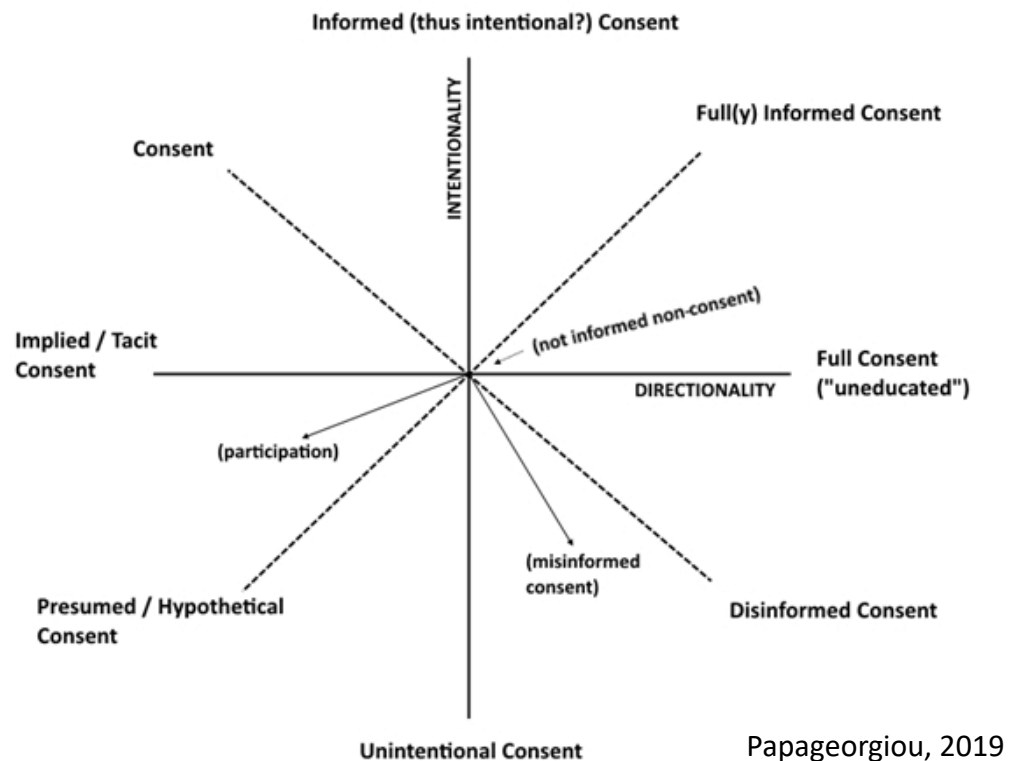
Patients want more control of their data:

- Consent should not be “forever.” People should have option to change their minds.
- Consent should involve how/if data are shared.
- Visibility leads to trust

**MY
DATA**



How “Informed” is Informed Consent?



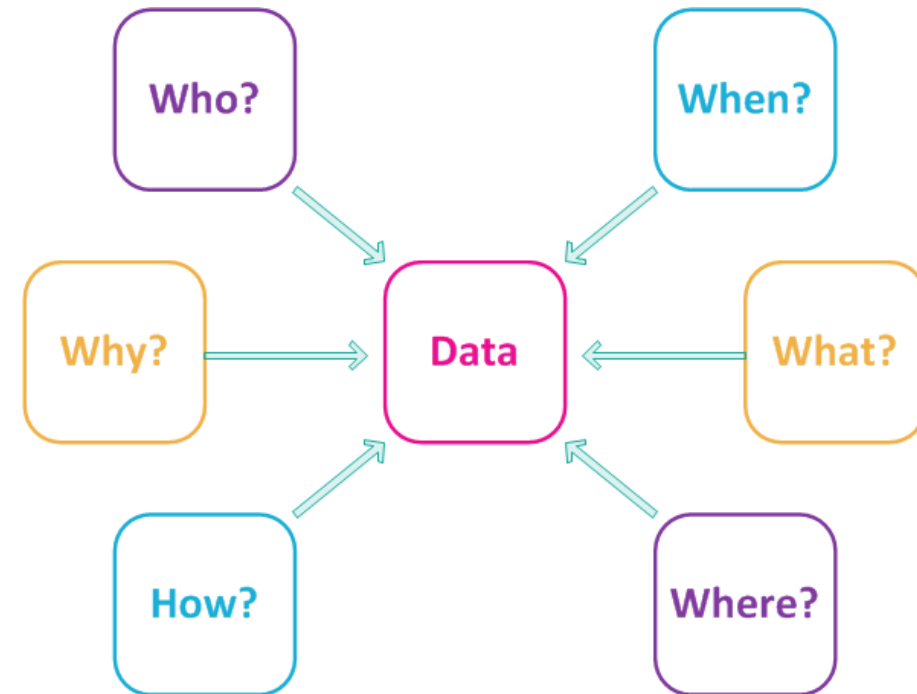
Papageorgiou, 2019

How can we ensure that dynamic consent is meaningful?

What features should we consider for success?

Literacy / Comprehension Considerations

- Technological literacy
- Written language limitations
- Medical / scientific literacy
- Information about choices is complicated
- Risk that individuals could newly gain or lose decisional capacity



Individual Behavior Considerations

Individual Behavior Limitations:

- The “privacy paradox”
- Individuals don’t read privacy information now. Why bother them with more information?
- Individuals over-estimate the nature of privacy
- Individuals under-estimate use of data
- Data anonymization may be somewhat of an illusion

Technological Considerations

- Digital divide persists
- Limitations to internet access / bandwidth
- Smart contract programming may fail
- Need for key management
- Must design technology to address GDPR and all applicable regulations



Life Sciences Research Considerations

- There are research exceptions in GDPR:
 - Need to maintain sufficient population distribution (to avoid “selection bias”)
 - Maintain safety information about all participants
- Debate about who “owns” patient/subject data
- Data use and consent permissions are widely interpreted
- There is no control over data already accessed and downloaded
- Risks and benefits of future research are often unknown at the time of consent

Boots on the Ground Problems

- Pervasive misunderstandings about blockchain
 - Public vs private chain capabilities
 - Hype
 - Cost
 - Untrusted environments
- Blockchain builds and questions are novel

What Legislators Can Do to Advance EU Blockchain

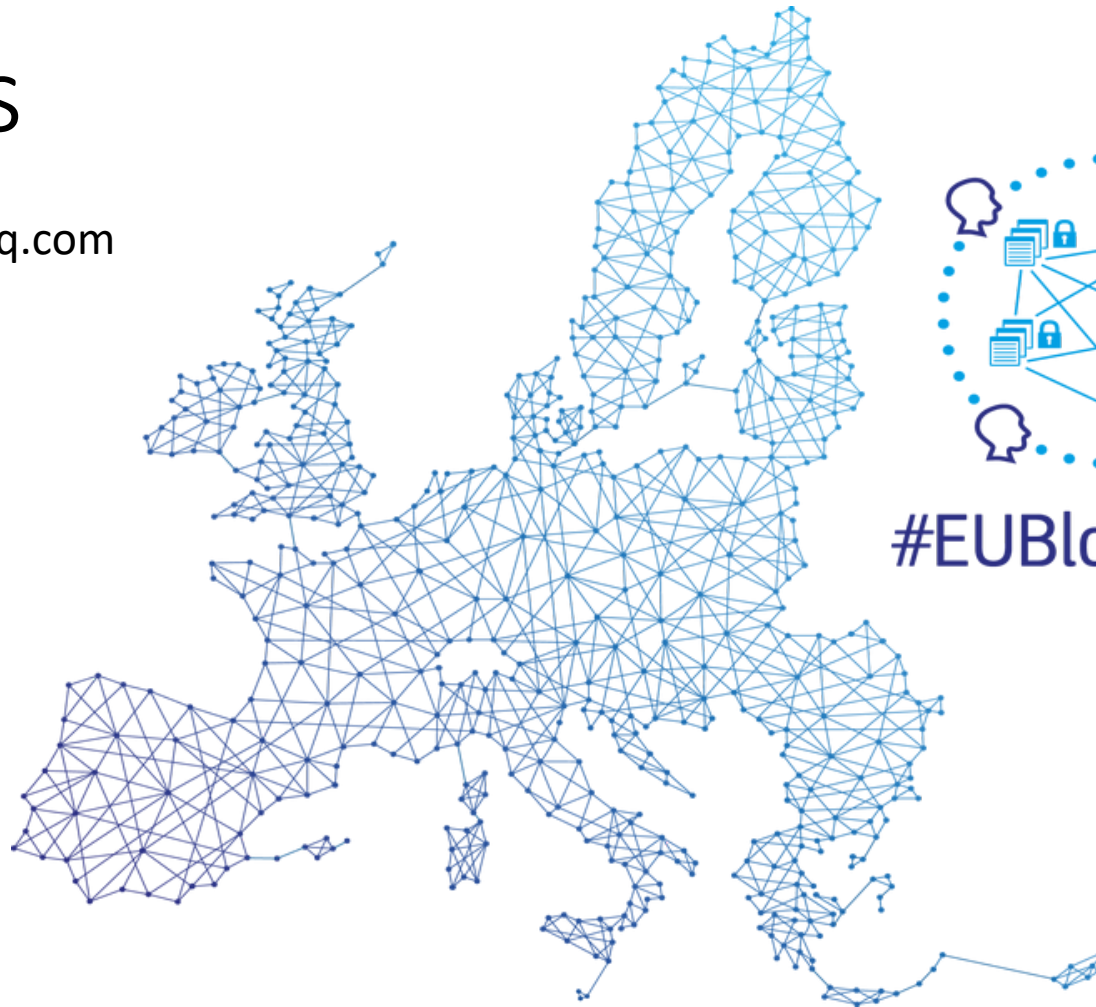
EU legislative guidance about:

- What blockchain technological solutions constitute “deletion” for GDPR compliance with the “right to be forgotten”?
- Are smart contracts on the blockchain legally enforceable?
- To what degree do Public IDs constitute personally identifiable info?
How about hashes resulting from an attestation?

Continue to become more educated about blockchain technology and its capabilities with dynamic consent and data management.

Questions

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#EUBlockchain

