A Blockchain-based Biomedical Consent Management Platform

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Introduction

The traditional way of managing bio-medical research participants consents lacks at some degree: integrity, operability, flexibility, and accessibility. These issues can reduce the patient's interest to provide consent and participate in bio medical research endeavors. Proposals like dynamic consent offer a new approach on how to handle communication between researcher and participate that possible could improve their engagement, safety, and data ownership. In a dynamic consent, the participant could follow what her data is used for and approve new research with already shared data (1). Current dynamic consent services aim to improve both transparency and trust in the participant-researcher relationship. These desired attributes correlate well with the inherited characteristic of blockchain technology (2). It would, therefore, be valuable to explore if blockchain could add any value in a dynamic consent application. Blockchain is a new evolving technology that have been proposed to improve data storage, access and security in a wide range of disciplines, including the health research domain. This technology, with its distributed ledger provides security through a cryptographic hash of previous records which will also provide data provenance, access and trust. Since most individuals like to provide consent without providing personal details and preferably keeping their identity hidden, this system could allow access in an autonomously, securely and possible anonymously way.

Informed consent in biomedical research

The current traditional way to manage how to involve patients and participants in research is a topic that has not kept up with the ongoing digitization and data-driven revolution within health care and health science. It is still a procedure that lacks a digital improvement, even in the most advanced health science and health care settings (often being done with paper). The main objective with obtaining informed consent from participants in a biomedical study is to ensure that the participants understand the purposes and risks with the

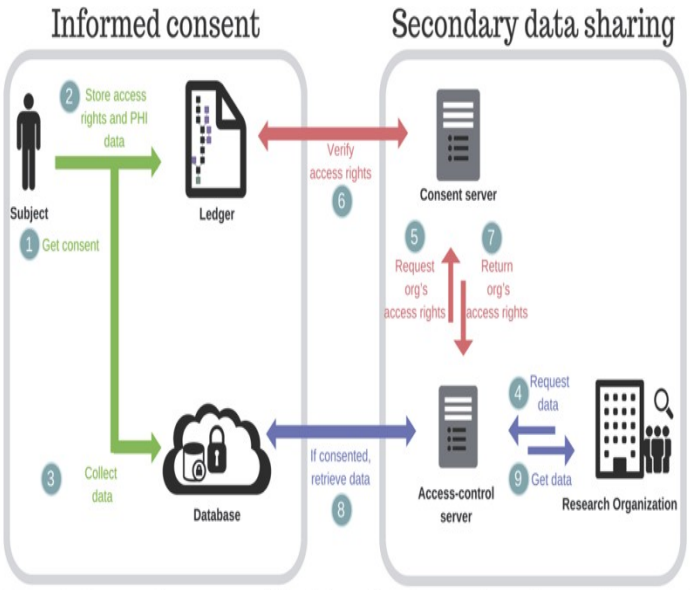

Figure 2: Design of our proposed blockchain-based system for enforcing IRB protocol. The workflow involves: (1) Subjects consenting to participate in the study. (2) Storing access rights for data sharing and PHI attributes of subjects on the ledger. (3) Storing data collected from subjects during the study in a database. (4) A third-party or research organization requesting to access data through access-control server. (5) Access-control server requesting consent server to verify access rights of the organization. (6) Consent server using smart contract to retrieve access rights stored on the ledger. (7) Consent server responding to access-control server with the access rights. (8) For a valid data request, access-control server fetching data from database. (9) Access-control server returning the data to research organization.

Figure 1: Informed consent [10]

research project, and ensure that they participate voluntarily with this knowledge. There are challenges with obtaining informed consent from participants; for example, participants often do not fully comprehend the content of the information sheet attached to the consent form. The consent form and information sheet are often lengthy and uses terminology not standard outside research or practiced medicine (3, 4). Often these consent forms are written on physical papers, and with that there are several challenges when it comes to safe storage, keeping records of several consents from the same participants, updating permissions and renewing consent for a different purpose. Especially challenging is these procedures in more extended cohort studies that often span several years, sometimes decades and usually conducted in multiple locations (5).

Dynamic Consent

Dynamic consent is best described as personalized, digitized communication platforms for facilitating consent management online (6). Active consent platforms should facilitate the whole consent process and enable a two-way communication with the researcher and participants where the participants and possible the researcher could remain fully anonymous where it is applicable. The platform should be able to handle different kinds of consent pending on the research objectives (1). Furthermore, a dynamic consent management platform provides researchers and participants with a full overview of the process back in time. Researchers should be able to audit and review procedures without the need to refer, handle, or file paper records. This aim to significantly reduce the time taken for audit and improve the reliability of the record trail (provenance).

There are several examples where biomedical (both clinical and population-based) research have used dynamic consent platforms (7, 8). Active consent has been proposed to increase the participant's comprehension of the consent process and make them more engaged in the research projects (1, 9).

Proposed system

We propose to develop a platform that provides a layer level access on collected patient consent. Other than removing the traditional way, the new proposal provides a system that manages the permission of the patient without high human involvement. The flexibility of the platform could potentially increases patients willingness to participate. The system shall provide the following essential features but not limited to:

- The consents (signature) of the participants should be linked to a research protocol
- The participants should be able to view their signed consent and the research protocol for, at least five years
- It the participants have signed several consents, an overview of all the signed consents should be given
- The participants should remain anonymous (possibly pseudonymous) on the chain
- The researcher should be able to notify the participants if a new consent is needed
- The participants should be able to retract her consent at any given time during the research project
- The researcher should be notified if a participant retract her consent
- An overview of the number of signed consents to a specific research protocol should be given

- A smart contract function tied to an ethical committee: Ethical approval should be given instantly, and only then, when signed consent from a predefined number of participants is obtained (optional)

Developing a platform using a public or consortium blockchain brings new features relative to the traditional way. Blockchain could be the foundation of a platform that can provide easy access, while the platform itself integrates security. The blockchain should provide the following attributes to the nodes in the network:

- All should have viewing access
- All should be able to obtain the full ledger at any given time
- Approved research institutes should have writing access.
- The consortium should vote to give new entities writing access.

To make our proposal into reality. We are planning to develop the platform using well-known blockchain technologies, most likely Hyperledger Fabric or Ethereum. Hyperledger Fabric is a permissioned blockchain network that set up by the organization to utilize a consortium. The organization that helped to set up the technology considered as a member, and they are responsible for the peer inside to participate in the network. Ethereum is an open source distributed public blockchain network. It allows decentralized apps to be built on with the help of smart contract functionality.

Expected results

The proposed system integrates blockchains and smart contracts to deliver the expected result. In this project, our primary focus will be on developing a platform that provides a user-friendly and highly secured service. The platform should provide the participant with full control of their consent(s) and at the same time facilitate an easy process for the researcher(s). This two trade-off will be designed and balanced so that the proposed system provides an efficient way of a patient consent management system. The outcome of the proposed method can be extensive, some of the expected outcomes are:

- Empower research participants by giving them a clear overview of their consents
- Making it easier for a researchers to ask for a new consent for new research or changes in the current research project
- Mitigate the risk of research protocols being modified after signed consent is obtained
- Enable stronger ethical soundness with transparency in the consent handling process

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