Introduction

Informed consent in research situations involves face-to-face interactions where verbal and written information about the research being performed is communicated to participants. The information that is communicated includes aims, benefits, risks, duration, procedure, use of data and confidentiality. These face-to-face approaches are costly, time-intensive, and require staff training, which are obstacles in the way of acquiring consent for data collection (Ivanova & Katsaounis, 2021). To overcome these obstacles, an e-consent tool that allows researchers and other entities to obtain dynamic consent from participants may present an effective solution. Dynamic consent is defined by an ongoing-two way interaction between participants and researchers where participants are highly engaged in the consent process. Participants in this process can opt in to research studies, projects and trials while having the right to monitor results of research and activities accomplished with their data (Ivanova & Katsaounis, 2021).

A key challenge before obtaining consent from participants is ensuring adequate disclosure about risks, benefits and consequences is given and understood (Lennox & Wright, 2019). Dynamic consent can be considered a complex behaviour because it requires multiple and ongoing actions from participants which requires behaviour maintenance and ongoing engagement from researchers (Parkinson, Schuster, & Russell-Bennett, 2016). Dynamic consent lacks a tangible incentive, requiring participants to envision a long-term distant benefit to their participation (Hall & Fong, 2007). Taking these factors into consideration, the Motivation-Opportunity-Ability (MOA) framework will be used to propose a number of solutions that will assist in facilitating the consent process where adequate disclosure is provided to participants, enabling a two-way interaction model between researchers and participants.

Consumer Demographics

Using the dimensions, 'concern for privacy', and 'technological and medical literacy', there are four archetypes for potential consumers, which describe barriers they may face. Group 1 (High Literacy, Low Concern) would be comfortable providing broad future consent, and Group 2 (Low Literacy, High Concern) who would be unlikely to ever interact with the website. Our solutions are mainly targeted at Group 3 (Low Literacy, Low Concern) and Group 4 (High Literacy, High Concern) where the use of dynamic consent is best facilitated. The main target demographic for this solution is consumers in Group 4, who are 'on the edge', specifically, a younger demographic who are familiar with technology but possibly unaware of the consent process, or their rights as a data holder.

A holistic platform - your data, your say

The proposed "web-based dynamic consent portal" should take consumers on a journey, educate them about consent in providing data, enable them to track their engagement with research projects, nudge them to give ongoing consent, and allow open communication with researchers. Our proposed solution presents four main components to the platform to facilitate this process.

VIDEO	SIGN UP	ALERTS	TRACK
INFORMATIVE + SIMPLE	CHOOSE LEVEL OF CONSENT	GIVE CONSENT	WHERE YOUR DATA IS USED
Inform & Enable	**Opportunity**	**Opportunity**	**Motivation**

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Component 1 - Video

The first solution we propose is creating a narrative video which utilises an analogy to simplify dynamic consent. Videos have been found to be useful in the consent process with dealing with medical research in the past (Lennox & Wright, 2019). Furthermore, we propose presenting multiple levels of consent which allow different types of data to be shared, allowing for cultural considerations and what information people are comfortable sharing. The video will simplify the consent levels, to be 'yes, I want to share my data', 'I want you to use some of my data', and 'no, but maybe later'. This messaging increases their ability, making the wanted behaviour more achievable and increases their self-efficacy in taking action (Parkinson et al., 2016). The video will utilise a humorous appeal, featuring simple animation and everyday language that is understood by the audience. The video will have closed captions for accessibility purposes. Importantly for first-time users, the video will appear as a pop-up when entering the site. Consequent visits will not feature the pop-up video, rather it will be retained as an option, for those who want to rewatch it.

Component 2 - Sign up - Give Consent

To streamline the process of consent, an initial sign up form that helps users choose the level of data they are comfortable sharing will be created. In the process of signing up, users will be asked to fill in their details (e.g., name, age, address) and choose from three levels of data consent: Level 1 to indicate a 'Strong Yes', Level 2 'Conditional Yes', and 'Maybe Later' and a no. The language will be intentionally positive, in order to encourage users to share data. This allows consumers to stay within their comfort zones by providing levels of choice for information that may be seen as highly private. This information is explained in detail in the video. Consent for future communication via email and/or SMS will also be asked in this form.

Component 3 - Alerts of new research projects

Researchers will be able to request data from eligible patients matching criteria for research purposes. Researchers can fill in the research project details within the template and publish it on the platform. On the platform, eligible participants will receive an alert of a new research project as a notification. Once clicked on to view the project, a pop-up will appear with an infographic summary of the project and level of consent required. The infographic will act as an executive summary using a pre-designed template that will use emotive language and a clear call to action. The summary will be presented outlining the goals of the research project and an explanation of what data is needed. At the end of the document, an indication of how many people signed up will be presented (e.g., 60% of this sample agreed to participate in this project). Users will then be given a simple 'yes' or 'not this time' options.

Component 4 - Track your data

In order to motivate participants to engage with research activities which involve sharing their data, a dashboard that shows individual participant data in research projects will be developed. The dashboard will show the number of projects a participant is currently involved in, how and where their data is used, any research they contributed to and how their data helped in each project. Digital badges, an intangible reward will be awarded based on the number of projects consented to.

Overall support

A chat function will be created to allow consumers to contact researchers related to the use of data and other concerns. Researchers and patients can send messages through the chat function related to the use of data and other concerns. This will assist in connecting researchers to data custodians, and patients to relevant information. The chat function can be automated with prepared answers for frequently asked questions. Automated responses will appear in real time, while other specific questions may be answered within a specific time frame (e.g. 24-48 hours). Users will be notified of response on the platform with a notification on the website, and if agreed to be contacted they may also be notified via email or SMS. The chat function will be available in the bottom right corner of most pages of the platform.

Evaluation

The performance of the solution can be tracked and tested in various ways. The rate of consent for research projects through the website can be compared to the rate of consent of research through previously existing Australian websites and in-person forms. The average number of research studies a patient engages in can be tracked and compared to other research to examine the long-term engagement levels of patients. Consumer satisfactions with various aspects of the website can be measured through consumer surveys and complaints. Engagement with the video can be examined through the amount of people who engage with the video and for how long. Researchers will be able to examine how long consumers read their executive summary and how long they spend reading each section in order to make more engaging executive summaries in the future.

References:

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