Insights from the Development of a Dynamic Consent Platform for the ATHENA Program: Original Paper

Eddy Xiong, Carissa Bonner, Amanda King, Zoltan Bourne, Mark Morgan, M. Ximena Tolosa, Tony Stanton, Kim Greaves

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Table of Contents

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Eddy Xiong[1*] BMedSci; Carissa Bonner[2*] BCom, BSc, MPH, PhD; Amanda King[3*]; Zoltan Bourne[4*] FRACGP, BMed, BSc; Mark Morgan[5] BM, BCh, MA, PhD, MRCGP, FRACGP; M. Ximena Tolosa[6*] BAgEng, PhD, MPH, MAE; Tony Stanton[7*] MBChB, PhD, FCSANZ, FESC, FRCP, FRACP; Kim Greaves[3, 8*] MBBS, BSc, M. App. Epid., FRACP

[1]Sunshine Coast University Hospital Queensland HealthSunshine Coast University Hospital Birtinya, QLD AU
[2]Menzies Centre for Health Policy and Economics School of Public Health, Faculty of Medicine and Health University of Sydney Camperdown, NSW AU
[3]The ATHENA Program Sunshine Coast University Hospital Queensland Health Birtinya, QLD AU
[4]Hinterland Health Maleny, Queensland AU
[5]Faculty of Health Sciences and Medicine Bond University Gold Coast, Queensland AU
[6]Communicable Disease Branch Queensland Department of Health Herston, Queensland AU
[7]Sunshine Coast University Hospital Queensland Health Birtinya, QLD AU
[8]National Centre for Epidemiology and Population Health ANU College of Health and Medicine Australian National University Canberra ACT AU
[*]these authors contributed equally

Corresponding Author:
Kim Greaves MBBS, BSc, M. App. Epid., FRACP
The ATHENA Program
Sunshine Coast University Hospital
Queensland Health
6 Doherty Street
Birtinya, QLD
AU

Abstract

Background: Dynamic Consent (DC) resolves many of the issues facing traditional paper-based or electronic consent including providing truly informed and engaged participants in the decision-making process. The Australians Together Health Initiative (ATHENA) Program aims to connect participants across Queensland, Australia with new research opportunities. At its core is the DC platform, an interactive and participant centric digital platform enabling users to view ongoing research activities, update consent preferences, and receive real-time feedback on research outcomes.

Objective: To describe the development process, construction, features, and testing of the ATHENA DC platform.

Methods: One-on-one interviews were undertaken with consumers followed by a workshop with key stakeholders to gain insights on the DC concept. Five problem statements were developed and solutions posed, from which a DC platform was constructed, tested, and used to recruit to a clinical trial. Feedback on user platform experience was gained from a survey hosted on the platform.

Results: Participants were positive about DC, valuing privacy, ease of use and adequate communication. Motivators for registration were feedback on data usage and its broader community benefits. Problem statements were security, trust and governance, ease of use, communication, control, and need for a scalable platform. Using the newly constructed DC platform, 99 participants were recontacted, of whom 59 logged on indicating use, and 22 registered for the clinical trial. Survey feedback was positive, reflecting satisfaction with clarity, brevity, and flexibility of the platform. Key barriers to implementation include technological and health literacy.

Conclusions: This study outlines the successful development and testing of a DC platform which was well-accepted, with users recognising its advantages over traditional methods of consent regarding flexibility, ease of communication, and participant satisfaction. This information may be useful to others who plan to use DC in healthcare research. Clinical Trial: NA

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Authors

Eddy Xiong, 1, 7

Carissa Bonner, 4

Amanda King, 1

Zoltan Bourne, 3

Mark Morgan, 6

M. Ximena Tolosa, 5

Tony Stanton, 1

Kim Greaves 1, 2

Institutional addresses

1. Sunshine Coast University Hospital, Queensland Health, 6 Doherty Street, Birtinya QLD, 4575

2. National Centre for Epidemiology and Population Health, ANU College of Health and Medicine, Australian National University, Canberra ACT 2600

3. Hinterland Health, Maple Street, Maleny, QLD 4551

4. Menzies Centre for Health Policy and Economics, School of Public Health, Faculty of Medicine and Health, University of Sydney, NSW 2006

5. Queensland Department of Health, Communicable Disease Branch, 15 Butterfield St, Herston, QLD 4001

6. Faculty of Health Sciences and Medicine, Bond University, Gold Coast, QLD 4229

7. School of Medicine and Dentistry, Griffith University, Gold Coast, QLD 4222

Corresponding Author

Kim Greaves

Kim.Greaves@health.qld.gov.au

+61 07 5202 7851

Abstract

Background:
Dynamic consent has the potential to address many of the issues facing traditional paper-based or electronic consent including providing informed and engaged participants in the decision-making process. The Australians Together Health Initiative (ATHENA) Program aims to connect participants across Queensland, Australia, with new research opportunities. At its core is the dynamic consent, an interactive and participant-centric digital platform which includes enabling users to view ongoing research activities, update consent preferences and provide ongoing engagement with researchers.
Objectives:
To describe the development of the ATHENA dynamic consent platform within the framework of the ATHENA Program including how the platform was designed, its utilisation by participants, and insights gained.
Methods:
One-on-one interviews were undertaken with consumers followed by a workshop with healthcare staff to gain insights on the dynamic consent concept. Five problem statements were developed, and solutions posed, from which a dynamic consent platform was constructed, tested, and used to recruit to a clinical trial. Potential users were randomly recruited from a pre-existing pool of 615 participants in the ATHENA program. Feedback on user platform experience was gained from a survey hosted on the platform.
Results:
Of the 13 consumers interviews undertaken, participants were positive about dynamic consent, valuing privacy, ease of use and adequate communication. Motivators for registration were feedback on data usage and its broader community benefits. Problem statements were security, trust and governance, ease of use, communication, control, and need for a scalable platform. Using the newly constructed dynamic consent platform, 99 potential participants were selected of whom 67(68%) were successfully recontacted. Of these, 59(88%) agreed to be sent the platform, 44(74%) logged on indicating use, and 22(57%) registered for the clinical trial. Survey feedback was favourable with an average 78% positive rating across all questions, reflecting satisfaction with clarity, brevity, and flexibility of the platform. Barriers to implementation include technological and health literacy.
Conclusion:
This study describes the successful development and testing of a dynamic consent platform which was well-accepted, with users recognising its advantages over traditional methods of consent regarding flexibility, ease of communication, and participant satisfaction. This information may be useful to others who plan to use dynamic consent in healthcare research.

Introduction

Rapid advances in medical knowledge, clinical trials and research have necessitated new and innovative requirements for obtaining informed consent. Dynamic consent is one proposed solution and is enabled by concurrent developments in technology [1,2].
Dynamic consent is a consent framework which encourages research participants to take a more active role when consenting to take part in research studies and clinical trials [3]. For example, participants can update their preferences in real time, and this can be managed through an online platform [4]. In doing so, studies can more effectively meet the legal and ethical standards which are ever-changing in the modern research environment and require a more flexible approach to ensure safety and autonomy [5]. The increasingly complex nature of studies such as those in the fields of genomics and epidemiology have given rise to much broader and more lengthy consent processes which have made it progressively more difficult for participants to understand the terms involved [6]. This results in a system which fails to adequately address participant understanding and comprehension [7,8]. Insufficient understanding of concepts in clinical trials is common due to the quantity and complexity of the information and can result in withdrawal of participation [7,9]. This has contributed to the great ‘connection’ issue affecting clinical trials regarding participant recruitment, retention, and engagement [10]. This reflects a failure on the part of the researchers to meet their needs by minimising participant burden, building trust, and ensuring comprehension of study goals and risks [11,12].

Since its initial proposal over a decade ago, dynamic consent has remained a topic of ongoing debate, and implementations are being trialled to build the evidence base to inform use [1,13,14]. Nevertheless, dynamic consent holds the promise of addressing many of these issues mentioned above. Operating on a web-based platform, the potential exists for participants to have higher levels of data control, be provided more information about outcomes and data reuse, as well as more interactive and engaging mediums of information delivery [15,16]. Being able to consent digitally has shown demonstrable benefits in engagement and comprehension of content compared to traditional consent processes [7]. Other features include the ability to provide and retract consent at will and in real-time, as well as providing a direct and ongoing communication link between participants and researchers. Due to its versatility, dynamic consent has been used in the generation of large-scale biomedical databases (biobanks) for research, containing the health information, including biospecimens of up to several hundred thousand of participants [16-18]. Past methods have traditionally relied on broad or blanket consent, a method that risks infringing upon participant autonomy, requiring careful consideration to meet ethical and legal requirements [19,20]. Dynamic consent potentially mitigates this by offering the possibility of consent choices, allowing specification of which information can be used for research [13]. Participants can also receive feedback on when, why and who has accessed their health information, and they are also able to withdraw consent or update their consent preferences at any time. Other applications include the ability to be prospectively consented to be contacted by researchers in the future, as well as being in control of the frequency of communications with researchers. These features mean participants can be more engaged in the decision-making process and aware of the broader significance of their contribution to the project, thus theoretically fostering greater satisfaction and retention when taking part in clinical trials [4,16,21].

The Australians Together Health Initiative (ATHENA) Program was conceptualised as a state-wide program for Queensland, Australia, with the central vision of engaging and connecting researchers and trialists with patients across the state, thus providing them with a comprehensive picture of

ongoing research activities, new treatment options, and opportunities to participate in research [22,23]. At the core of this approach is dynamic consent which aims to systematically engage and recruit over 1 million people attending the health system. ATHENA focuses on obtaining consent on two crucial fronts. Firstly, participants are invited to share access to their health information with the state government health department. This includes data from primary care providers, hospitals, and health registries, as well as any routinely collected administrative health registry information, for research purposes. Secondly, ATHENA actively seeks consent to allow for the recontact of participants, leading to the formation of a substantial cohort of research-willing participants. The resultant health data collection can be screened to rapidly identify and contact eligible participants for clinical trials and/or research studies, thus streamlining the whole trial design and recruitment process. This has the potential to solve the significant recruitment challenges that currently plague clinical research both nationally and internationally [11]. The benefits of the ATHENA program for patients are access to additional treatment options, a more active role in research, improved population health, access to personalised, mutually beneficial research opportunities, and long-term engagement with the research community. For researchers, the program offers an enhanced study design, efficient and rapid participant recruitment, reduced risk and cost in recruitment, simplified research processes, expanded research exposure, and facilitate beneficial inclusions within grant applications. In 2020, ATHENA successfully undertook the ATHENA Coronavirus Disease (COVID-19) feasibility study aimed at generating a cohort of patients diagnosed with COVID-19 in Queensland who had consented to provide a comprehensive set of their clinical information including linked general practice, hospital and other registry health information, as well as consent-to-recontact [22,23]. The purpose of the study was to provide a cohort of patients who could be re-contacted for future COVID-19-related research, test the ATHENA concept, and gain some understanding of the epidemiology of patients with COVID-19.

Although relatively new, several other groups globally have successfully integrated a dynamic consent platform into their existing research infrastructures. The consent platform developed for ATHENA possesses several features which distinguish it from other platforms. Unlike its counterparts [16, 17, 24, 25], the ATHENA dynamic consent platform has been developed with the future capability for broad-scale, mass-recruitment in mind, rather than being disease- or trial-specific. It also takes a relatively systematic rather than opportunistic approach to participation with registration being offered as part of routine hospital care. Another difference is that it requests linkage of health information for unspecified research in the future and introduces consent-to-recontact.

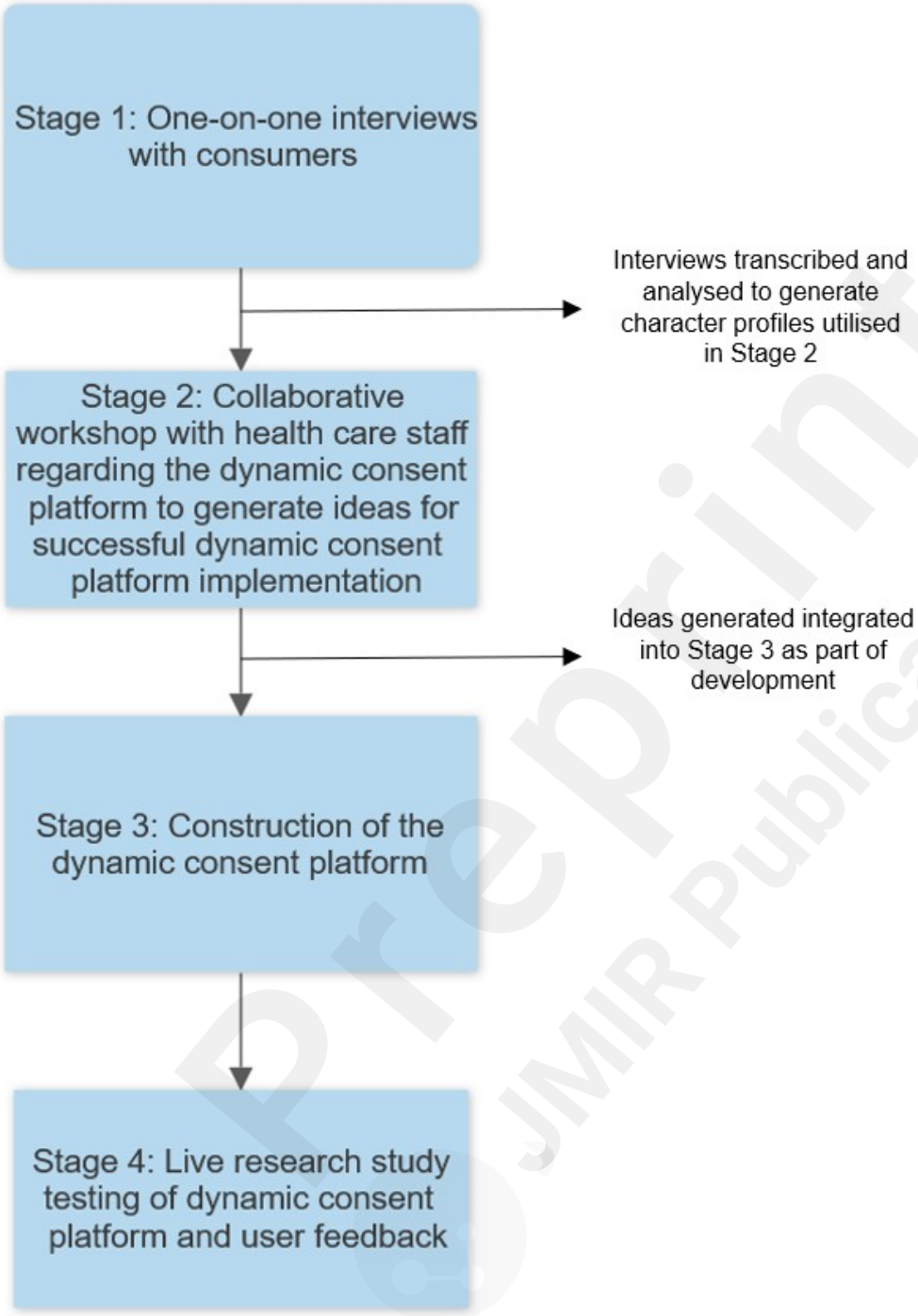
This report aims to describe the development of the ATHENA dynamic consent platform within the framework of the ATHENA Program [22] including how the platform was designed, its utilisation by participants, and insights gained. The intention is that this information may be useful to those who wish to develop a dynamic consent platform for future medical research.

Methods

The development and testing of the ATHENA concept and dynamic consent platform was divided into four stages (Figure 1): (1) one-on-one interviews with consumers regarding dynamic consent in the context of the ATHENA Program; (2) collaborative workshop with health care staff for insights regarding the dynamic consent platform; (3) construction of the dynamic consent platform; (4) live research study testing of dynamic consent platform and user feedback.

Figure 1: Flow chart of the development and testing process for the Australians Together Health

Initiative (ATHENA) dynamic consent platform.



Stage 1: One-on-one interviews with consumers regarding the concept of dynamic consent in the context of the ATHENA Program

The first stage of development was outsourced to the Digital Innovation Hub within Queensland Health who undertook one-on-one interviews with consumers with specific consideration given to consumer opinions on the concept of dynamic consent within the ATHENA Program. Participants were recruited from an established pool of volunteers and through advertisements run at the local hospital and health service. Participants were selected to represent a broad range of demographics,

including: (1) participant(s) from culturally and linguistically diverse, indigenous, and Caucasian communities; (2) a range of ages from 21 to 74 years; (3) participants living in rural and urban communities; (4) a variety of professions including manual workers, carers, information technology (IT), and two general practitioners.

Individuals were interviewed separately, for a one-hour duration, semi-structured, and assisted with a discussion guide centred around several key areas: health and technology literacy; understanding of data privacy and trust in security measures; the concept of dynamic consent and data sharing; motivation to sign up to the ATHENA Program and barriers to recontact.

A summary of the discussion guide can be seen in Figure S1 in Multimedia Appendix 1 [26]. Interviews were conducted either in-person or using online video call and recorded. Interviews were transcribed and thematic analysis performed to extract several broad themes representative of beliefs held by participants. These themes were used to generate several different character profiles which demonstrating the differing opinions regarding dynamic consent, the ATHENA Program and broader themes identified. Character profiles were additionally ascribed demographics such as occupation, residence, and age. These were an amalgamation of interviewees beliefs and did not represent any specific individual and played a role in the second stage of dynamic consent platform construction by providing examples of potential types of users for consideration.

Stage 2: Collaborative workshop with health care staff regarding the dynamic consent platform

This stage involved a one-day workshop involving guided group discussions with key stakeholders from health care. The character profiles from Stage 1 were presented to the group, and several prompts and activities were enacted to encourage discussion and consideration of various aspects of the dynamic consent model. Key discussion points centred around roadblocks hindering access to the dynamic consent platform for users, as well as any potential solutions. Participants were encouraged to generate a set of ‘problem statements’ which would be necessary constituents of a successful dynamic consent platform and then asked to propose potential solutions or features that would address these statements. The knowledge gained from this workshop was then integrated into the design of the dynamic consent platform.

Stage 3: Construction of the dynamic consent platform

Using the information gained from Stages 1 and 2, the ATHENA dynamic consent platform was constructed by eHealth Queensland. To meet local ethics requirements, the use of the dynamic consent platform required compliance with Queensland Health legal and cybersecurity standards. Consultation with both Queensland Health cybersecurity and legal teams were undertaken.

Stage 4: Live research study testing of dynamic consent platform and user feedback

The cohort of the ATHENA COVID-19 study consisted of 995 participants who had had been diagnosed with COVID-19 of whom 842(85%) were successfully contacted and reached a consent decision regarding re-contact. Of this cohort, 615 (75%) consented to future recontact to discuss participation in COVID-19 related research trials or dynamic consent participation [22]. Due to resource constraints, a proportion of these (n=99) were randomly selected to be re-contacted to consent to test the dynamic consent platform. Each participant was contacted via telephone to ask if

they would agree to receiving information about a new research study - the COVID OZ-Genetics Research Project [27]. Those who expressed interest and consented were registered on the dynamic consent platform and emailed a login link with a password. The web link to the platform was then emailed separately to participants asking them to log in using the details provided. Upon signing into the platform, participants were presented with a summary of the new clinical trial opportunity: the COVID OZGenetics Research Project. Interested participants were prompted to go through a short series of steps on the platform requesting consent to have their contact details released to the COVID OZGenetics trial team, who would then contact them to discuss the study in more detail. The COVID OZGenetics Research Project is a study run by the University of Queensland, investigating genetic factors that may predispose to long COVID [27]. Whilst on the dynamic consent platform, participants were also invited to complete a 5-point Likert survey that provided feedback on their experience using the dynamic consent platform, which is a modified version of a published survey [26]. Response options available were ‘strongly agree’ (1), ‘agree’ (2), ‘neither agree nor disagree' (3), 'disagree’ (4) and ‘strongly disagree’ (5).The questionnaire and answer key can be viewed in Table S1 in Multimedia Appendix 1. A Checklist for Reporting Results of Internet E-Surveys checklist was also completed and can be viewed in Table S2 in Multimedia Appendix 1 [28].].

Ethics approval for this study was granted by the Gold Coast Hospital and Health Service Human Research Ethics Committee (reference HREC/2020/QGC/63555); and the Australian National University Human Research Ethics Committee (reference: 2020/312).

Results

Stage 1: One-on-one interviews with consumers regarding the concept of dynamic consent in the context of the ATHENA program

Thirteen one-one-one interviews were conducted and participant demographics are summarised below in Table 1:

Table 1: Demographics of participants interviewed for development of the Australians Together Health Initiative dynamic consent platform.

Participant Demographics	N (%)
Total number of participants	13 (100)
Gender	
Male	6 (46)
Female	7 (54)
Age	
18-24	1 (9)
25-34	2 (15)
35-44	2 (15)
45-54	2 (15)
55-64	2 (15)
65-74	4 (31)
Residential Location	
Urban	9 (69)
Rural	4 (31)

Identifies as Aboriginal and Torres Strait Islander (yes)	1 (9)
Relationship with Technology	
‘It helps me a lot in my life, but I don’t need it all the time’	2 (15)
‘I use it mostly for work’	2 (15)
‘I use it for a range of things, but it doesn’t feature much in my life’	2 (15)
‘I love it all’	5 (39)
‘I hardly ever use digital technology, but I know it’s there if I ever need it.	2 (15)

Four themes were identified through thematic analysis of interviews: (1) Consent and control. Participants identified that it would be important for them to be able to play a role and have control in the sharing of identifiable data. They were supportive of a digital platform which would be an effective means of enabling them to update their preferences in real time, so long as assurances were made regarding data security. (2) Motivations to register, benefit to community and feedback on outcomes. Multiple participants noted that financial incentives would not be an effective motivator for registration. The notion of receiving feedback and updates regarding the outcomes of their participation in the study was met with enthusiasm and participants expressed that this would be a good motivating factor to participate. Several participants observed that this was a point of dissatisfaction with previous trials they had participated in. They stated that after their involvement finished, they were never informed about the outcome or results of the trial. It was also noted that if it could be demonstrated that their participation was of benefit to the health of the wider community, this would likely be the greatest motivator for registration. Interviewees also identified that easy access and registration on the platform was important. The majority also stated that recommendation from their general practitioner to register with ATHENA would play a significant role in their decision to sign up. (3) Data privacy and communication. Participants identified both the benefits that sharing their data would bring, as well as the potential risk for data breaches. The desire for assurance that their data would be safely stored was a common theme. There was a relatively high level of trust placed in the government and Queensland Health to maintain data security. Participants also had strong opinions on their preferences for the frequency of contact from researchers, identifying that this should be something that can be personalised during the registration process. (4) Dynamic consent. Participants were universally positive about the concept of dynamic consent. They demonstrated an understanding and appreciation of its benefits and how this would allow for many of the conditions outlined above to be met. Many expressed the opinion that participant consent should be acquired whenever the sharing of information is involved, and acknowledged that a dynamic consent platform, if operated correctly, would be an effective means to accomplish this.

Six character ‘profiles’ were generated which are presented in Table 2, representing both the common themes and beliefs identified through thematic analysis, as well as any potential fringe beliefs and ideas regarding dynamic consent identified in the interviews conducted.

Table 2. Summary of amalgamated character profiles generated from one on one interviews conducted for the ATHENA program, each expressing differing opinions regarding dynamic consent.

Background (Age years, Occupation, Location)	Security/trust	Sharing of data	Communication	Summative quote
50 Tradesman.	Open minded about data	Would sign up to the platform	Minimal contact preferred.	“Data can be good, like when I had a work safety

Lives rurally.	sharing	if they saw benefits of the platform	Emails only	compensation case, it helped me get the facts and get sorted"
21 Information Technology worker. Lives near the city.	Does not want data being shared unless it is relevant for their health	Happy to share data if it is anonymous	Would wait to see demonstrable benefits before registering	"If I can't do it online with the data, then I won't do it at all. I spend most of my time connected to something"
43 General Manager - technology company. Lives in the city.	Expresses concerns regarding security and transparency around personal data	Identified there are many positives with sharing data. Would be annoyed if data was shared without consent	Would like to have communication regarding what data is being shared	"I need to know the governance and protective measures for my data"
70 Retired. Semi-Urban.	Has "nothing to hide" and is not concerned about data privacy	"If the data can help someone else, then just do it"	Would like to know how their data is used. "It is important to close the loop"	"I don't worry about privacy when it comes to my information. I think sharing of this data is very necessary and I would just let it happen"
32 Product developer. Lives in the city.	Trusts the government to store and share data securely	Happy to share data as long as it is not identifiable	Would like to be consented for absolutely every study	"Data is a powerful tool and can be used to better or worsen the world"
40 Unpaid volunteer. Lives in community housing.	Trusts the government with their data. "If you can't trust them, who can you trust?"	Happy to share data as long as it cannot be used to discriminate against them	Would use GP as their point of communication. Great deal of trust in their GP	"I am happy to share my data to help someone else, but I want it anonymised"

Stage 2: Collaborative workshop with health care staff regarding the dynamic consent platform

Six healthcare staff were involved in the workshop and included a medical consultant, a general practitioner, an IT specialist, a clinical trials nurse specialist, a clinical nurse, and a senior manager representing clinical trials and research for Queensland Health. Several factors were identified that would be important in ensuring the successful uptake of dynamic consent. From these, five central 'problem statements' (listed below) were generated by workshop participants to aid further discussion and development. (1) Security, trust and governance. Users should be able to trust that their information is safe, secure, and appropriately governed, so that they can be confident their information will only be used by the right people, for the intended purpose. (2) Ease of use. Users should be able to intuitively navigate the platform and get simple, clear guidance and information on the research trials available. This enables them to be better informed when making decisions about

the platform. Additionally, a specific issue identified was the lengthy nature of participant information consent forms, compounded by insufficient health literacy. Stakeholders identified that patients often feel overwhelmed and confused by the inconsistency of formats presented in consent forms, the burden of form filling, and the difficulty in finding a suitable study to participate in. (3) Control. Users should be able to easily sign up to the platform on any device, manage their preferences, stay engaged with the platform and be able to opt out so they have full control of their information. (4) Ease of communication. Users should be able to easily communicate with researchers and staff to take part in research trials or provide feedback or progress on research outcomes, saving time on recruitment and maintaining engagement. (5) Scalable system. Queensland Health staff and researchers should have access to a scalable, adaptable system which can be utilised for other types of consent such as for health procedures.

Workshop participants were then asked to propose solutions to the problem statements which are summarised in Table 3.

Table 3: Solutions proposed by health care staff to manage problem statements arising from the ATHENA dynamic consent workshop, and whether they were incorporated into new platform build.

Problem statement	Section of platform	Solution	Incorporation into final platform build (Yes/No)
Ease of use Ease of communication	General platform features	Must be a web application or an app that is intuitive and self-explanatory.	Yes
		Ability to send text messages/email to participants.	Yes (email)
Security, trust and governance Ease of communication.	Login	Secure authentication system	Yes
		Frequently asked questions section – (For instance, regarding data usage)	Yes
		Progress bar for sign-up (estimation of time remaining)	No
Ease of use Control	About you (personal page)	How many trials the participant is already involved in	Yes
		What research papers their data has contributed to.	No
		Virtual medals or other rewards for incentivising and rewarding participation.	No
		Easy withdrawal section/ or opt out	Yes
Security, trust and governance	Who the ATHENA Program is supported by.	General Practitioners	Yes
		Royal Australian College of General Practitioners	Yes

		Primary Health Networks	Yes
		Queensland Health	Yes
		Heart Foundation	No
		Cancer research	No
Ease of use	Participant information sheet and consent form	As simplified as possible	Yes
		Use drop-down menus that reveals lists of options or sections	Yes
Ease of use	What's new section	Outline of what new trials are available	Yes
		Ability for patient to search for a trial related to a specific condition	No
Ease of communication	Contact us section	Refer a friend or relative	No
		Contact details	Yes
		Help desk	Yes
		Chatbot	No
Security, trust and governance Scalable system	Back end (the component of dynamic consent platform inaccessible to the user that is necessary for operation)	Audit trail	Yes
		Participant profiling	No
		Automated release of data from GP straight to Queensland Health upon consent	No
Ease of use Ease of communication	Information or landing page	Introductory video	No
		Description of the dynamic consent platform/ATHENA[a]	Yes
		Frequently asked questions section	Yes
		Strong purpose statement – How will participant's involvement help?	Yes
Ease of communication	Help and Support	Chat box- connects participant to staff member	No
Ease of use	Continued engagement	Badges or rewards for participation	No
Security, trust and governance	Other considerations	End user testing	Yes
		Death data linkage so participants who have passed away are not	No

Control Scalable system.		contacted mistakenly, or alternatively so their next of kin may be contacted.	
		Legal & ethics review	Yes

[a]ATHENA: Australians Together Health Initiative

Stage 3: Construction of the Dynamic Consent Platform

Architectural Information Technology Concept Design
An architectural IT concept design (Table S3, Multimedia Appendix 1) for the dynamic consent platform was drawn up by eHealth Queensland containing the core requirements and solutions identified from Stages 1 and 2. It was the intention that most of these features were to be implemented in the pilot platform trialled in this study. Those not implemented were due to time and cost restrictions and would be implemented in a later version of the platform (Table 3).

Dynamic Consent Platform Construction
The dynamic consent platform was built using a healthcare intelligence solutions platform already in use by the Queensland public health system to ensure scalability. This platform enables the acquisition and analysis of performance analytics, data visualisations, as well as user experience analytics. This is crucial to enable the project to better understand user engagement, demographics, retention, and behaviour. All data was stored in Queensland Health and all data changes audited and can be viewed via comprehensive audit logs.

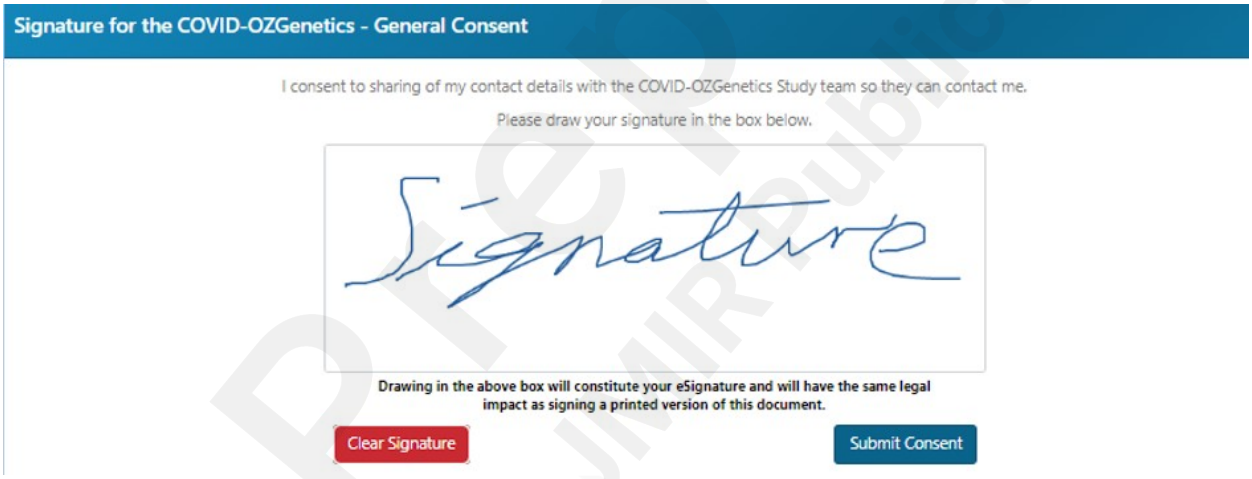
There are three different user groups who will use the platform: general users (participants), platform reporting/dashboard users, and administrator users. General users can create new consent choices and provide input for surveys. Reporting/dashboard users are responsible for day-to-day operation of the platform and can create new dashboards and run reports. Administrators have full access to create new content such as records and study templates and are responsible for updating content as required (for example, for newly available clinical trials or changes to existing trials). They can review actions made by participants such as study project choices, emails requested, and survey submissions. They can edit some features of the website such as menu and list views. Importantly, no users have the capacity to edit consent responses.

The platform was designed with clarity and accessibility in mind. Initially, users are brought to an information page with an introduction and frequently asked questions. After registration, a landing page for the dynamic consent platform is presented (Figure 2), from which studies available to participate are visible. Upon selecting a study, the user is presented with the title and details of the study. Consent is submitted via a digital signature (Figure 3) , and participants are provided a digital receipt which can be viewed within the dynamic consent platform. They will also be sent a confirmation email with a PDF copy of their submitted consent. Participants can withdraw consent. A full set of images demonstrating this registration process can be seen in Figure S2 in Multimedia Appendix 1.

Figure 2: Image of the landing page for the ATHENA dynamic consent platform webpage. ATHENA:

Australians Together Health Initiative. COVID-19: Coronavirus Disease.

Figure 3: Image of a sample digital signature consent form on the Australians Together Health Initiative (ATHENA) dynamic consent platform webpage.



Legal and Cybersecurity compliance

Advice from Queensland Health legal and cybersecurity teams were incorporated into the build to ensure that the platform met the required standards. Legal requirements necessitated compliance with multiple ‘Health Acts’ and the completion of a ‘Privacy Impact Assessment’ [29-33]. Cybersecurity required that safety standards were complied with regarding the collection, storage and use of participant information; that appropriate levels of administrative and technical security provisions were adopted to protect the personal information stored in or used by the platform; and that Australian Privacy Principle 4, of the Australian Privacy Principles Act, were met [31].

Stage 4: Live Research Study Testing of Dynamic Consent Platform and User Feedback

99 participants were identified of whom 67(68%) were successfully recontacted. Of these, 59 (88%) agreed to be sent the dynamic consent platform and 8(12%) declined; 44(75%) logged onto the platform indicating use. 25(57%) of these expressed interest in the new research study and gave

consent for their contact details to be released to the OZGenetics study team. No participants actively refused consent. 17(68%) participants completed the post-trial survey regarding experiences with the dynamic consent platform and general feedback. Figure S3 in Multimedia Appendix 1 summarises the flow of participant recruitment. Table 4 summarises the participant response rates of the recruitment process. For simplicity, responses (1) and (2) are grouped into ‘agree’, response (3) is ‘neutral’, and responses (4) and (5) are grouped into ‘disagree’.

Table 4: Survey responses regarding the ATHENA dynamic consent platform usability collected after a trial of the platform (n=17)

Question	Response		
	Agree	Disagree	Neutral
My overall experience using this website was good	76% (13)	12% (2)	12% (2)
It was easy to navigate the website	76% (13)	12% (2)	12% (2)
The length of time it took me to complete my consent choice was too long	18% (3)	71% (12)	12% (2)
The information presented to me in the consent choice process was clear	82% (14)	12% (2)	6% (1)
The amount of information provided to allow me to make a consent choice was just right	88% (15)	12% (2)	0% (0)
I felt pressured to complete the consent process	6% (1)	94% (16)	0% (0)
I liked the opportunity to be able to provide consent choices	71% (12)	6% (1)	24% (4)
The number of consent choices provided to me were just right	76% (13)	6% (1)	18% (3)
I felt positively about the opportunity to ask questions and provide feedback to the research team	71% (12)	6% (1)	24% (4)

Discussion

This study describes the development of a dynamic consent platform within the framework of the ATHENA program. A multi-faceted research methodology was used to explore the acceptability of the program, including the processes involved in the development and testing of a dynamic consent platform, one-on-one consumer interviews, workshops with healthcare staff, construction of a dynamic consent platform, and testing within an active research study. Key findings from the perspective of participants were control of data, feedback, communication, and data privacy. It also reflected that participants were broadly receptive to the concept of dynamic consent if implemented appropriately. Stage 2 translated this information into a set of problem statements with practical solutions which could be directly incorporated into the construction of the platform. Following construction of the platform (Stage 3), Stage 4 demonstrated that by implementing these features, we were successful in creating a platform whereby 75% of those participants who agreed to be sent the platform, logged on, indicating use. In addition, the platform from received positive feedback from users who completed the survey.

The Role of Dynamic Consent and Comparison with Prior Research

Although the ATHENA dynamic consent platform concept received positive acceptance by the public, this was subject to certain conditions. These included having control over data, use of data for public benefit, feedback on use of health information, and ensuring privacy especially where identifiable data was used. The use of dynamic consent was widely accepted as a means to achieve this, with participants cognisant of its potential advantages over paper or simple electronic based consent, and how its use might meet the many conditions described above. Our methodology identified that participants have a strong preference towards being able to exercise control of the distribution of personal data which is consistent with the literature [6,16]. As dynamic consent is only as effective as its users' willingness to engage with the platform, it is imperative such needs are met. In our platform, this was realised through a flexible consent model that enables digital consent, withdrawal, and revision of consent in response to new data requests. Past research is supportive of dynamic consent as a means to bypass the need for broad consent, as well as a means to enable greater participant autonomy [4,35]. Perhaps one of the most important motivating factors identified in Stage 1 for participants regarding engagement and registration, was that they receive feedback on usage of their data. Underpinning this is the importance of regular communication which forms the foundation of a trust-based partnership between participants and researchers and has historically been difficult with paper-based consent. Meeting this requirement is made possible through the dynamic consent model, which allows for flexible and minimally invasive communication [4,15-17]. Additionally, participants in Stage 1 expressed strong preferences on the frequency of contact from researchers, and as such it is evident that a tailored approach to communication is necessary and that this is an important factor in determining their likelihood to engage with the program.

Contemporary studies regarding dynamic consent support the notion that the model is best realised with a patient-centric design process [36,37]. The CHRIS study used a dynamic consent platform to recruit opportunistically through advertising, a closed cohort of 13,000 participants. In contrast, the ATHENA Program concept requires ongoing, at scale, systematic recruitment which requires a predominantly self-intuitive engagement process [16,23,38]. Users will be able enter the registration process through means such as hyperlinks and Quick Response (QR) codes. While not fully realised yet, this differs from the CHRIS study which required invitation of participants to a study centre and close guidance by research assistants present throughout the enrolment process [16]. Also, unlike the ATHENA dynamic consent platform, withdrawal from the CHRIS study was only available by contacting the study centre. Other examples of dynamic consent platforms such as that of the ADDN, utilise recruitment systems which are opportunistic in nature, requiring clinicians to identify relevant patients and then explain the concept of the platform, in order to recruit new participants. This may hinder the recruitment process as it requires significant external input in prompting and registering patients [36].

Our report also provides information on the accessibility and usability of the dynamic consent platform, derived from surveys of users logging in and trialling the platform themselves. In our study, 68% of participants who gave consent to be re-contacted were successfully contacted which is similar to our previously reported re-contact success rates using e-consent [23]. A larger proportion participants in our study logged on to the platform compared to other groups such as CTRL who reported <20% dynamic consent platform registration rates [39]. The reasons for this are not clear but possible reasons are as follows. In CTRL, their 'retrospective cohort' were re-contacted via email which differs to our study in which patients were telephoned and this may have affected consent rates. In our study, all patients were pre-registered on the consent platform whereas in CTRL, patients had to register themselves. Finally, in CTRL the cohort had genetic disorders and required

consent to genetic research which is a more complex process involving watching a video and answering 13 mandatory and 21 optional consent choices. In our study, the cohort consisted of patients who had COVID-19 previously, and there were only two consent choices with an optional survey.

This adds to the small but growing pool of literature on the utility of dynamic consent [38,39]. Notably, the ATHENA dynamic consent platform differs from other studies in that it requests access to all of a person's health information including that from primary care. It also does not focus on any specific group or category of disease, and instead aims to indiscriminately recruit as much of the population as possible over an indefinite period of time. This contrasts with other studies that target specific groups of patients, or recruit over specific time periods such as the Rare and Undiagnosed Diseases Study, ADDN (patients with Type 1 diabetes mellitus), CHRIS (Genomic research) and CTRL (Genomic research) [4, 16, 17, 36].

Implications for Policy and Practice

The ATHENA Program is now ready for implementation in hospitals and health services in Queensland. Previous pilot studies and feasibility assessments, including the ATHENA COVID-19 study, have demonstrated both its operational capabilities and initial effectiveness within smaller contexts [22,23]. Complementing this, an independent economic report on the ATHENA Program, has confirmed the program's financial sustainability in terms of return on investment. The next phase involves refining the dynamic consent platform, incorporating insights from this report and introducing enhanced user authentication mechanisms. These include self-registration, robust user verification utilizing government-issued identification and two-factor authentication, ensuring secure access. Another development goal is implementing a post-trial feedback mechanism, empowering participants with insights into the utilization of their data. Additionally, incorporating QR code-based access and registration is necessary to facilitate mass consent. Our study required an initial telephone step in which patients previously registered with the ATHENA COVID-19 study were re-contacted to ask if they were interested in receiving information about a new research study, and then emailed a login link and password. In the proposed ATHENA program, unregistered patients attending hospital clinics, wards and procedural areas will be presented with access to the ATHENA website and invited to login and consent. The authors believe a certain level of human assistance will always be required at certain contact points when using dynamic consent to improve patient experience and ensure maximal recruitment. In the ATHENA Program although human contact will be kept to a minimum, hospital staff will be trained to prompt and invite patients to access the website. Those patients who wish to participate but are unable or unwilling to use dynamic consent will be offered paper-based consent. Staff will also have a level of training so they can explain the ATHENA concept and advise on website access. Furthermore, any patients requiring more information will be invited to telephone the ATHENA information centre serviced by ATHENA staff.

Limitations

This study required patients be telephoned and provided with the platform weblink and login details which does not specifically replicate the future intended user experience in a hospital setting. The study also involved a relatively small sample size which may affect generalisability. Extensive consultation was undertaken with Health Consumers Queensland, First Nations and culturally and linguistic diverse leaders in the community regarding the ATHENA COVID-19 concept, the ATHENA program, its protocols (including the use of electronic consent), and patient information consent forms. However, the development of the dynamic consent platform was more limited in

scope and did not include detailed consultation with these priority groups. Consequently, the validity of its use in these populations is limited. Recognising this, subsequent platform iterations will involve comprehensive consultations with these groups to co-design a platform with maximum utility and to avoid exacerbating existing inequities in these populations.

Conclusions

This study outlines the development of the ATHENA dynamic consent platform within the framework of the ATHENA Program. It describes the evolution of the platform, its utilization by participants, and the insights gained from this process. The findings showed positive reception, hinging on participant data control, research for the benefit of population health, feedback mechanisms, and protection of data privacy. The platform was well-accepted, highlighting its advantages over traditional methods in regard to flexibility, ease of communication, and participant satisfaction. We hope that this information is useful to other groups who plan to develop a dynamic consent platform for use in healthcare research.

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Availability of data and materials

Datasets used and analysed during this study are available from the corresponding author upon reasonable request.

Disclosures

There was no generative AI used in any portion of the writing of this manuscript.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Abbreviations

ADDN:	Australian Diabetes Data Network
ATHENA:	Australians Together Health Initiative
CHRIS:	Cooperative Health Research in South Tyrol
HREC:	Human Research Ethics Committee
IT:	Information Technology
QR:	Quick Response
RUDY:	Rare UK Diseases Study
COVID-19:	Coronavirus Disease

Multimedia Appendix 1: Supplementary figures and tables

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Supplementary Files

Untitled.
URL: http://asset.jmir.pub/assets/c8bda30e73a8a25e06474f987424a0ae.docx

Figures

Flow chart of the development and testing process for the Australians Together Health Initiative (ATHENA) dynamic consent platform.

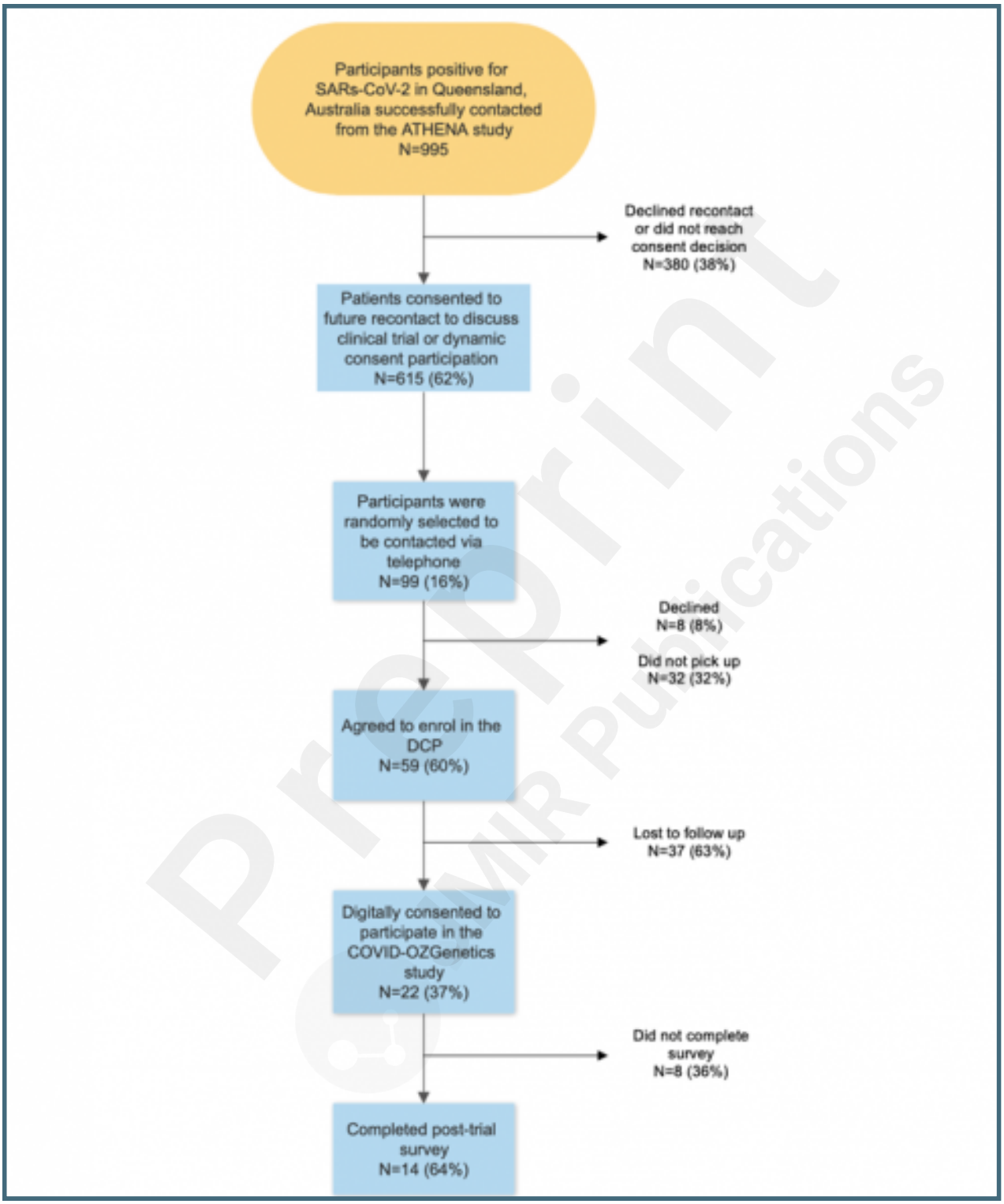

Image of the landing page for the ATHENA dynamic consent platform webpage. ATHENA: Australians Together Health Initiative. COVID-19: Coronavirus Disease.

Image of a sample digital signature consent form on the Australians Together Health Initiative (ATHENA) dynamic consent platform webpage.

Multimedia Appendixes

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CONSORT (or other) checklists

CHERRIES.
URL: http://asset.jmir.pub/assets/f426b8df516a3738b3612fdcb2ecaa59.pdf

ICHECK-DH Checklist.
URL: http://asset.jmir.pub/assets/24062779b9f771d15890d7bf67d84b5c.pdf