

# e-Consent in Biomedical Research Registries: A GDPR-Compliant Approach Explored in the Context of the Australasian Diabetes Data Network

Zhe Wang<sup>a</sup>, Anthony Stell<sup>b</sup>, Jean Paul Vera Soto<sup>c</sup> and Richard O. Sinnott<sup>d</sup>  
School of Computing and Information Systems, The University of Melbourne, Melbourne, VIC 3010, Australia

**Keywords:** e-Consent, Biomedical Registries, GDPR, ADDN, Type-1 Diabetes.

**Abstract:** e-Consent - the digital capture of a patient's consent to be involved in medical research - is a feature of biomedical research that is becoming increasingly prevalent with the advance of digital technology to support clinical/biomedical research and targeted registries. Although there have been many reviews of e-consent over the past decade - evaluating aspects such as informed consent, engagement, comprehension and data security - there remain unanswered questions about how e-consent fits in the context of recent data legislation and privacy demands such as the European General Data Protection Regulation (GDPR). This paper outlines key aspects of e-consent in the context of GDPR and the specific demands placed on biomedical registries used for diverse research objectives. We present a practical realisation of GDPR e-Consent in the context of the Australasian Diabetes Data Network (ADDN) – the national type-1 diabetes registry for Australia.

## 1 INTRODUCTION

Informed consent is a foundational part of biomedical research ethics according to the Belmont Report (1979)<sup>1</sup>. This introduced three key elements: information, comprehension and voluntariness that should be considered for informed consent to ensure the protection of human subjects in research. Such principles have guided the evaluation of different consent processes (Sugarman et al., 1998)(Del Carmen and Joffe, 2005). Traditionally, this process was dominated by paper-based methods, where individuals physically sign documents after discussions with their healthcare providers. However, with the advent of electronic medical records and advancements in digital technology, the electronic format of informed consent (e-Consent) is gaining attention. Review papers of e-Consent have explored multiple domains including general healthcare (Chimonas et al., 2023), surgical procedures (Mirza et al., 2023) and biomedical research (Cohen et al., 2023)(De Sutter et al.,

2020)(Skelton et al., 2020). In healthcare and surgical contexts, e-Consent mainly aims to streamline administrative undertakings, elevate the standard of care, and enrich the patient experience (Mirza et al., 2023).

In the field of biomedical research, different categories of registries are often used to store and process electronic medical information extensively. There are various types of registries including *biobanks*, *clinical trial registries*, *population registries*, and *targeted disease registries*. **Biobanks** are repositories that store biological samples for use in research. These are often managed according to professional standards (Hewitt and Watson, 2013). The NSW Health Statewide Biobank<sup>2</sup> and Australian Health Biobank (AHB)<sup>3</sup> are two such exemplar biobanks in Australia. Biomedical samples are collected to advance future research discoveries based on access to physical specimens, e.g. for targeted genomic analysis. **Clinical Trial Registries** such as the Australian New Zealand Clinical Trial Registry (ANZCTR)<sup>4</sup> keeps track of clinical trials being undertaken in diverse research areas. **Disease Registries** collect targeted data about

<sup>a</sup> <https://orcid.org/0000-0001-6054-6468>

<sup>b</sup> <https://orcid.org/0000-0003-4819-9883>

<sup>c</sup> <https://orcid.org/0000-0001-6345-5596>

<sup>d</sup> <https://orcid.org/0000-0001-5998-222X>

<sup>1</sup> [www.hhs.gov/ohrp/regulations-and-policy/belmont-report/](http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/)

<sup>2</sup> <https://biobank.health.nsw.gov.au/>

<sup>3</sup> <https://www.csiro.au/en/work-with-us/industries/health/australian-health-biobank>

<sup>4</sup> <https://anzctr.org.au/>

individuals who have a specific disease together with how they are being treated. The Australasian Diabetes Data Network (ADDN)<sup>5</sup> is a disease registry focused on collecting type-1 diabetes data from across Australia and New Zealand. Unlike other registries, ADDN directly re-uses *existing* health data from hospitals and centres, i.e., as opposed to requiring manual data entry to a separate registry. Such registries are used to help researchers observe patterns, understand diseases, and improve treatments and disease management guidelines at scale. Integrating consent mechanisms into biomedical registries is increasingly seen as a pivotal step in ethical research (Win and Fulcher, 2007).

A recent review (Skelton et al., 2020) shed light on the current e-Consent landscape by presenting a workflow of the informed consent processes (shown in Figure 1. The right-hand side of the workflow illustrates how digital informed consent typically works in biomedical research. It comprises three elements of informed consent: information, comprehension and voluntariness which are supported by different digital tools. However, the workflow is abstract and does not consider the fine-grained and evolving privacy regulations of different countries. For example, in the U.S., the HIPAA (Health Insurance Portability and Accountability Act)<sup>6</sup> was issued by the US Department of Health and Human Services (HHS) in 1996. It introduced HIPAA Authorization for Research<sup>7</sup> which requires researchers and healthcare organisations to obtain written authorisation from individuals before using their health information for research purposes. The European Union’s General GDPR (General Data Protection Regulation)<sup>8</sup>, which was put into effect in 2018, offers the most advanced privacy legal framework. It takes the protection of personal data, including health-related information, to a much finer-grained and patient-oriented perspective. The consent conditions for GDPR require that consent is freely given, specific, informed, unambiguous, and easy to withdraw (also known as *the right to be forgotten*). GDPR is more structured and stringent compared to HIPAA and empowers individuals in how “their data” might be used or not as the case might be. In Australia, the health data sharing landscape has largely been shaped by the Privacy Act 1988 (The Act)<sup>9</sup>. This is currently being amended to align with GDPR and

other international frameworks (Australian Government, 2022).

In this context, biomedical research registries need to design their electronic consent processes to be aligned with stringent legal requirements while keeping a delicate balance between individual privacy, research safety, and broader public interest (Win and Fulcher, 2007). Our work aims to augment the e-Consent workflow (Figure 1) delineated by (Skelton et al., 2020) with concrete examples of what it looks like to capture and enforce e-Consent in a GDPR-compliant manner in a specific biomedical registry: the Australasian Diabetes Data Network (ADDN) that is used for diverse research interests.

## 2 BACKGROUND

### 2.1 ADDN Background

Australia has one of the world’s highest rates of type-1 diabetes (T1D). By September 2022, over 134,000 individuals with T1D were registered with the National Diabetes Service Scheme (NDSS)<sup>10</sup> in Australia. To better understand and manage this health challenge, the Australasian Diabetes Data Network (ADDN - [www.addn.org.au](http://www.addn.org.au)) was launched. It was funded by the Juvenile Diabetes Research Foundation (JDRF – [www.jdrf.org.au](http://www.jdrf.org.au)) in 2012. The ADDN registry consolidates longitudinal data from 59 diabetes centres from across Australia and New Zealand, capturing extensive records from more than 20,000 patients. This includes over 250,000 hospital visits.

ADDN’s primary mission is to collate T1D health data from various centres into a single platform. This unified database helps monitor long-term patient outcomes, advance T1D research, and enhance clinical care across Australasia. The University of Melbourne’s Melbourne eResearch Group (MeG – [www.eresearch.unimelb.edu.au](http://www.eresearch.unimelb.edu.au)) maintains and supports the ADDN registry.

Figure 2 shows an example of a subset of the patient data based on the ADDN schema. As noted, ADDN re-uses existing health data from hospital systems. The health data is de-identified at source before it is populated into the ADDN registry, a Unique Subject Identifier (USI) is generated using the BioGrid data linkage platform ([www.biogrid.org.au](http://www.biogrid.org.au)). This identifier replaces personal identifiers whilst ensuring that data remains traceable for clinical or research

<sup>5</sup>[www.addn.org.au](http://www.addn.org.au)

<sup>6</sup><https://www.hhs.gov/hipaa/index.html>

<sup>7</sup><https://privacyruleandresearch.nih.gov/authorization.asp>

<sup>8</sup><https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679>

<sup>9</sup><https://www.legislation.gov.au/Details/C2014C00076>

<sup>10</sup><https://www.ndss.com.au/about-the-ndss/diabetes-facts-and-figures/>

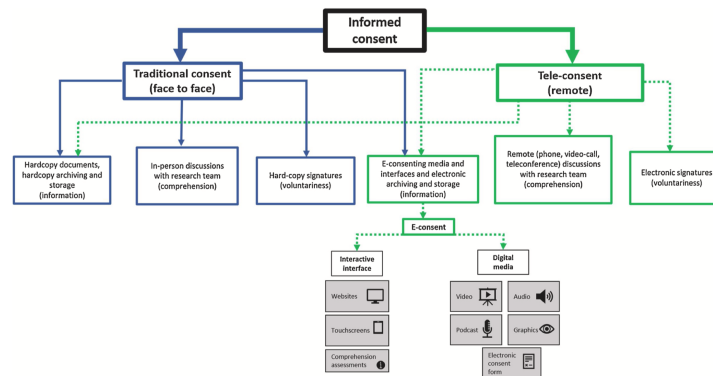


Figure 1: Workflow of informed consent processes from (Skelton et al., 2020).

```

<patient>
  <centre>MEG</centre>
  <localId>23</localId>
  <dateOfAddnConsent>2022-01-01</dateOfAddnConsent>
  <dateOfBirth>2000-12-27</dateOfBirth>
  <sex>FEMALE</sex>
  <diabetesType>TYPE_1</diabetesType>
  <dateOfDiagnosis>2010-11-01</dateOfDiagnosis>
  <countryOfBirth>1101</countryOfBirth>
  <preferredLanguage>1200</preferredLanguage>
  <dkaAtDiagnosis>false</dkaAtDiagnosis>
  <currentPostcode>2770</currentPostcode>
  <bioGridId>1234</bioGridId>
</patient>
    
```

Figure 2: Example of patient data based on the ADDN schema.

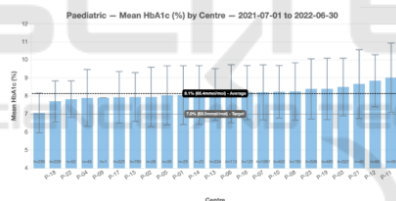


Figure 3: Example of a site-specific benchmarking report.

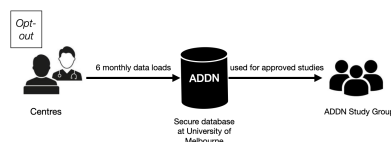


Figure 4: ADDN consent process diagram.

purposes without compromising the privacy of the individuals.

Figure 4 shows the basic process of the current ADDN consent mechanism. Rather than seeking explicit permission, e.g., signing a consent form or ticking a consent box from each individual (opt-in), patients are automatically included in the registry unless they actively choose to opt-out. The opt-in/opt-out consent status is captured by clinicians and/or nurses who provide them with healthcare during hospital visits. As part of this process, they are presented with all of the details of the ADDN project and explanations

of the consent process. This consent capture has historically been realised by a signed letter. If a participant chooses not to opt-out after being provided with this information, the date on which an individual decides not to opt-out (and thereby passively provides consent) is documented. This is shown as “*dateOfAddnConsent*” in Figure 2.

After recording the “*dateOfAddnConsent*”, patient data is transmitted to the ADDN registry by centres. This occurs twice per year. This action indicates “by default” that the data is authorised for use in subsequent research studies. Such downstream use of the data is unbeknownst to the patients. This is not aligned with GDPR, however. As part of ADDN, centres receive a site-specific benchmarking report as shown in Figure 4 illustrating how their centre compares to other centres across a range of metrics, e.g., average HbA1c for patients at their centre compared to other centres for example).

Centres and researchers more generally also have the opportunity to propose studies using the aggregated T1D data from ADDN. Projects undergo an ADDN-specific approval process decided by an ADDN Study Group<sup>11</sup>. However, patients are not informed about these projects, hence there is a lack of patient awareness regarding research initiatives using their data.

## 2.2 Background to Consent

Based on a systematic review conducted by (de Man et al., 2023), it was found that opt-out procedures tend to yield higher consent rates and result in more representative participant samples when compared to opt-in procedures. This is because opt-out procedures do not require individuals to take proactive steps to provide consent. However, it may raise ethical concerns about personal autonomy when participants are un-

<sup>11</sup><https://www.addn.org.au/governance>

aware of their participation and the subsequent, downstream use of their data. (Williams et al., 2015) discuss the legality of opt-out consent, which can decrease potential participation due to unwarranted misconceptions and associated risks thereby impacting the validity of research outcomes.

Additionally (de Man et al., 2023) identified that opt-in studies utilizing broad consent tend to achieve higher consent rates compared to study-specific consent projects. Study-specific consent has been criticised for potentially causing consent fatigue (Dankar et al., 2020)(Ploug and Holm, 2015)(Holm and Ploug, 2017), since participants receive high volumes of consent requests so that the choice will become routinised and/or cause them to refuse or withdraw consent due to the volume of requests (Dankar et al., 2020)(Holm and Ploug, 2017).

However, it is important to note that while broad consent offers advantages in terms of a lower administrative burden, (Haas et al., 2021) identified that broad consent models raise privacy issues regarding personal data, potentially resulting in reduced participation rates in studies. This reduction in participation rates could also lead to participants feeling as though they have less control over their data, ultimately giving rise to trust and ethical concerns (Mamo et al., 2020).

The one-off opt-out consent model provided to ADDN patients remains in place unless patients proactively contact the ADDN project manager to make changes to their registry status. Patients have the option to leave the information collected so far but not permit further collection (partial opt-out) or request deletion of all information collected (full opt-out). This approach lacks ongoing patient engagement and involvement in dynamic decision-making. When centres send their data to the ADDN registry, patients are not informed about it, nor do they have access to the data being collected on them, or the opportunity to express their preferences regarding the data use in specific downstream studies.

This lack of ongoing interaction between patients and the broader research community and the use of one-off static consent overlooks the dynamic nature of biomedical research for several reasons. For example, the notion of “personal data” is not static and data can be easily repurposed (Ausloos, 2012). Some biomedical research registries such as longitudinal studies require the ongoing collection of biological samples and health-related records (Lee and Lee, 2022). The future usage of data is often not static following initial data collection (Kaye et al., 2015)(Mamo et al., 2020), particularly in rapidly evolving fields like biotechnology. As a result, par-

ticipant preferences may evolve with changing values and aspirations (Mascalzoni et al., 2022) and legality across different jurisdictions in cross-border research may evolve.

The existing opt-out, broad, one-off consent framework for ADDN gives rise to many issues, especially with regard to frameworks such as GDPR. When assessed against the three pillars of the Belmont Report<sup>12</sup> — information, comprehension, and voluntariness—the current mechanism is predominantly aligned with the left-hand side of the workflow depicted in Figure 1., as shown in the consent process diagram (Figure 4), patients receive information through a physical patient letter, comprehension is facilitated by discussions between the clinician and patients during regular visits, and the exercise of voluntariness is limited to opt-out options.

These challenges are further compounded by research demands such as linking ADDN data with external datasets such as the Australian Institute of Health and Welfare’s<sup>13</sup> national death index, the Australian medical benefits scheme<sup>14</sup>, and the Australian pharmaceutical benefits scheme<sup>15</sup>. To facilitate this, introducing more personal identification into ADDN is essential to avoid exacerbating technical, ethical, and legal issues.

Given the shift to more rigorous privacy regulations in Australia, it is imperative to design the consent workflow with GDPR compliance in mind, to offer participants better control over downstream use of their personal data. The existing ADDN consent model, as represented on the left-hand side of the workflow in Figure 1, is incompatible with GDPR standards. In the subsequent sections, we delve deeper into the specific conditions of GDPR consent and highlight gaps in the current framework and how to augment the right-hand side of the workflow (e-consent) to better capture consent in a GDPR-compliant manner for biomedical research registries such as ADDN.

## 2.3 The GDPR Context

Article 4.7 and 4.8 of GDPR provides definitions for two crucial roles within the data processing ecosystem. The **‘Data Controller’** is the entity responsible for determining the ‘why’ and ‘how’ of processing personal data. In the case of a biomedical research registry, for example, the institution overseeing the

<sup>12</sup>[www.hhs.gov/ohrp/regulations-and-policy/belmont-report/](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/)

<sup>13</sup><https://www.aihw.gov.au/>

<sup>14</sup>[www.mbsonline.gov.au](https://www.mbsonline.gov.au)

<sup>15</sup>[www.pbs.gov.au](https://www.pbs.gov.au)



registry's operations would be considered the Data Controller, as it decides the purposes and methods for collecting and storing biological data.

The '**Data Processor**' is the entity performing actual actions on behalf of the Data Controller. In a biomedical research registry scenario, an IT or data management company contracted by the project to process associated data would typically assume the role of Data Processor.

GDPR broadly defines a '**data subject**' as any living individual whose personal data is collected, held, or processed by a particular organisation.

In the context of ADDN, the roles of data controller and data processor are delineated among various collaborating entities. The direction and purpose of ADDN operations are primarily shaped by the ADDN governance team. This team comprises independent external investigators, ADDN investigators, representatives from JDRF<sup>16</sup>, and a group of patient advisors. Meanwhile, the actual processing of patient data — transferring it from hospital systems and ensuring its alignment with ADDN's governance policies — is managed by the software developers of the Melbourne eResearch Group (MeG). Within the GDPR's framework, every living patient registered within ADDN falls under the definition of a 'data subject'.

According to Article 7 of GDPR, consent only becomes legally valid when it satisfies the five conditions listed below:

“(1) **Freely Given** - the data subjects must not be cornered into agreeing, noting that the imbalance between the data subject and controller can often making unencumbered consent difficult, e.g., patients may feel obliged or have concerns that the treatments they receive may be inferior if they do not agree. Furthermore, each use of personal data should be given separate consent.

(2) **Specific** – the consent must be collected for certain agreed activities or purposes unless explicitly identified as “general” research.

(3) **Informed** - the data subject must fully understand the implications of consent before making a decision. This includes an understanding of data processing activities, their purpose and any associated risks or consequences.

(4) **Unambiguous** – it should be immediately clear whether a data subject has consented. Consent under GDPR cannot be implied or assumed, rather explicit opt-in consent is required.

(5) **Withdrawal** – individuals can withdraw their consent at any time, and this withdrawal should be made as easy as obtaining the original consent. This

<sup>16</sup>[www.jdrf.org.au](http://www.jdrf.org.au)

should result in the removal/deletion of their data from the registry.”

Based on the GDPR's five consent conditions, an ideal consent process in the realm of biomedical research should evolve into a patient-centric, continuous, opt-in, and dynamic engagement mechanism. This not only maintains GDPR compliance but also grants individual's autonomy over use of their data.

## 2.4 Australian Privacy Law

In Australia, the health data sharing landscape has predominantly been shaped by the Privacy Act of 1988 (The Act)<sup>17</sup>. Recently in September 2023, the Australian Government unveiled its response<sup>18</sup> to the Privacy Act Review Report (Feb 2023)<sup>19</sup>. This is the culmination of two years of extensive consultation and review resulting in the release of Issues Paper (Oct 2020)<sup>20</sup> and Discussion Paper (Oct 2021)<sup>21</sup>.

In this response, the government's stance on privacy has been clarified, showing alignment with numerous proposals designed to enhance privacy safeguards for individuals.

One of the key points has been the area of consent. Aiming to alleviate burdens on individuals and avoid *consent fatigue*, the government has given in-principle agreement to Proposal 11.1 which seeks to refine the definition of consent, emphasising that it must be voluntary, informed, current, specific, and unambiguous. Moreover, with Principle 11.3, individuals are given the clear empowerment to withdraw their consent, insisting that the withdrawal process should be as straightforward as giving the consent process.

These developments in Australian privacy standards align with the consent conditions of the GDPR, underscoring their global relevance and prominence. Given these evolving legal landscapes, it is paramount for Australasia-based research initiatives such as ADDN, to improve their consent mechanisms. By aligning with these contemporary standards, not only will they be adhering to domestic regulations but this will also ensure compatibility with international norms, driven by GDPR.

To realise this vision, a digital platform — poten-

<sup>17</sup>[www.legislation.gov.au/Details/C2014C00076](http://www.legislation.gov.au/Details/C2014C00076)

<sup>18</sup>[www.ag.gov.au/rights-and-protections/publications/government-response-privacy-act-review-report](http://www.ag.gov.au/rights-and-protections/publications/government-response-privacy-act-review-report)

<sup>19</sup>[www.ag.gov.au/integrity/consultations/review-privacy-act-1988](http://www.ag.gov.au/integrity/consultations/review-privacy-act-1988)

<sup>20</sup>[www.ag.gov.au/rights-and-protections/publications/review-privacy-act-1988-cth-issues-paper](http://www.ag.gov.au/rights-and-protections/publications/review-privacy-act-1988-cth-issues-paper)

<sup>21</sup><https://consultations.ag.gov.au/rights-and-protections/privacyact-review-discussion-paper/>

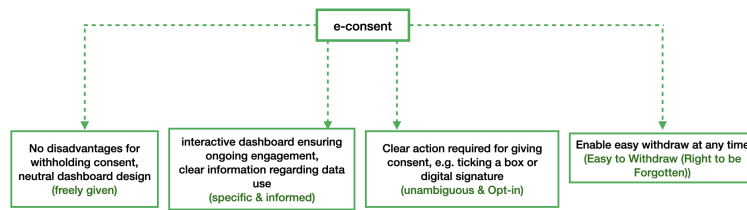


Figure 5: Augmented e-Consent workflow.

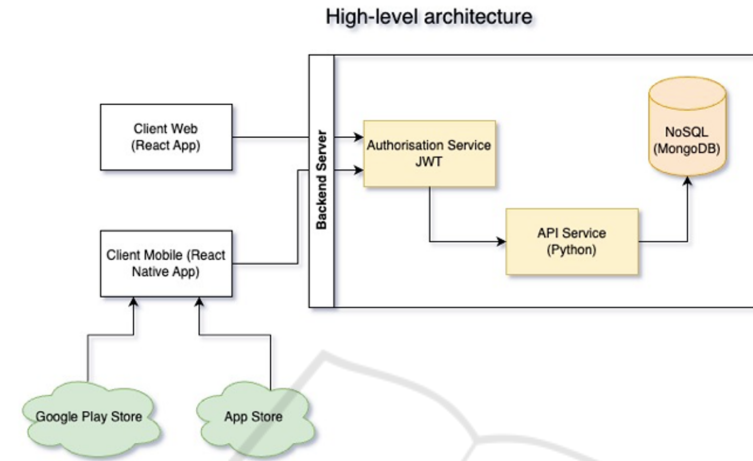


Figure 6: High-level architecture of ADDN Consent app.

tially in the form of a web or mobile app — is essential. This app should not only provide patients with an interactive interface but also grant them direct access to their data. They could then comprehend their information, and based on this, decide if they consent to its use in specific research projects on an ongoing basis. The traditional consent process represented in the left-hand side of (Skelton et al., 2020)’s workflow for e-consent in Figure 1 would never support such dynamic and evolving systems. Furthermore, different from the right-hand side of Figure 1, this model goes beyond just digital signatures or list of digital media. Rather it is about designing a continuous, informed, and interactive relationship between the patient and the ongoing use of their data.

### 3 E-CONSENT WORKFLOW

As discussed above, we have refined the workflow presented by (Skelton et al., 2020) as shown in Figure 1. The augmented tree diagram in Figure 5 underscores the foundational pillars of GDPR consent, essential for an e-Consent platform. Extended from the “information, comprehension and voluntariness” requirements, each branch of the tree represents one of the main GDPR consent conditions and the critical requirements and features that e-Consent platforms

should integrate to ensure GDPR compliance. This illustration offers practical implementation suggestions suitable for real-world applications. Guided by our augmented workflow, the subsequent sections detail the specific requirements of the e-Consent platform in the ADDN context.

## 4 ADDN IMPLEMENTATION

### 4.1 Overview

To improve the current consent process as described in section 2, we introduce the ADDN eConsent mobile app, as detailed in (Wang et al., 2022)(Wang et al., ). Figure 6 shows the high-level architecture of the application. At the heart of the backend system lies the Authorisation Service JWT (JSON Web Tokens). This service controls the authentication processes, ensuring that only authorized users and services can access the required data.

Building on this foundation, the platform supports a Python-based API Service. This service serves as a conduit between the Authorisation Service and the underlying data store, which is realised as a NoSQL MongoDB. The MongoDB database provides the scalability and flexibility needed to store vast amounts of data pertaining to users, consent data,

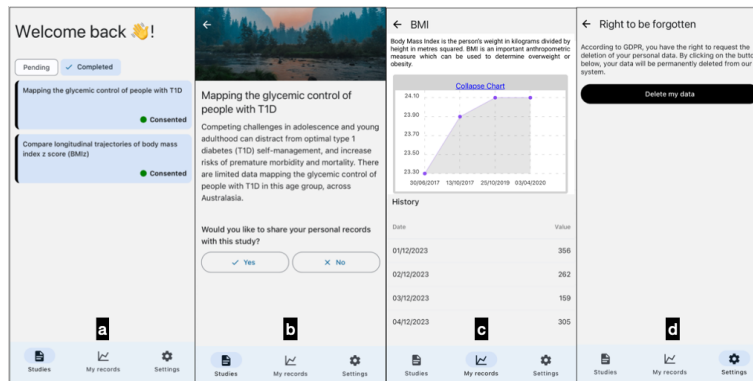


Figure 7: Screenshot of ADDN Consent Mobile Application.

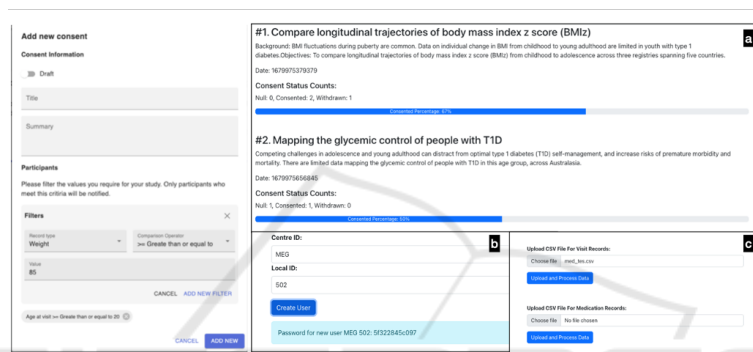


Figure 8: (Left) Screenshot of web application: create a research study (right) Screenshots of web application: Consent statistics (a), create a user (b) and upload user's data.

and details of research studies. The Python API Service handles the communication between the database and the client-side applications. In addition, its architecture allows connections with external databases, which can be a valuable feature in future iterations.

For the front end, there are two clients: the React Web Application (Figure 8) is primarily designed for the ADDN administrative team clinicians, and the React Native Mobile Application is tailored for the end-users and is where the actual consent processes take place.

During a patient's regular visit, the clinician will explain the ADDN project and the usage of the ADDN consent app. Once the patient agrees to use the app, the clinician will prepare it for the patient, as shown in Figure 8(b), with an activation code being generated for security log-in.

When an ADDN research study is approved, the administrator can dispatch consent tasks to target groups as shown in Figure 8 (left) and a notification indicating a new consent task will be sent to the target users via their mobile application. They can also monitor the progress of different consents across various research studies Figure 8 (right(a)). The interface ensures that admins can keep track of all ongo-

ing activities and make decisions swiftly. At the same time, patients are fully aware of the projects that are requesting access to and use of their data and can accept or refuse such requests on an ongoing basis.

## 4.2 The Consent App

In this section, we use a table (shown in the Appendix) to outline the specific consent requirements associated with the five GDPR conditions based on the augmented e-Consent workflow presented in Section 3. These requirements inform the design of a compliant and functional e-Consent system.

The e-Consent app offers the "My Records" dashboard, where patients can access and review their clinical data. As illustrated in Figure 9, patients can retrieve their visit and medication data directly on their devices. This provides them with direct access to the data captured about them that exists within the ADDN registry. This not only reinforces the principle of data accessibility but also serves as an added incentive for patients to engage with the app. For example, they can track key health indicators such as their HBA1c levels over time or their BMI.

It is noted that to comply with the freely given

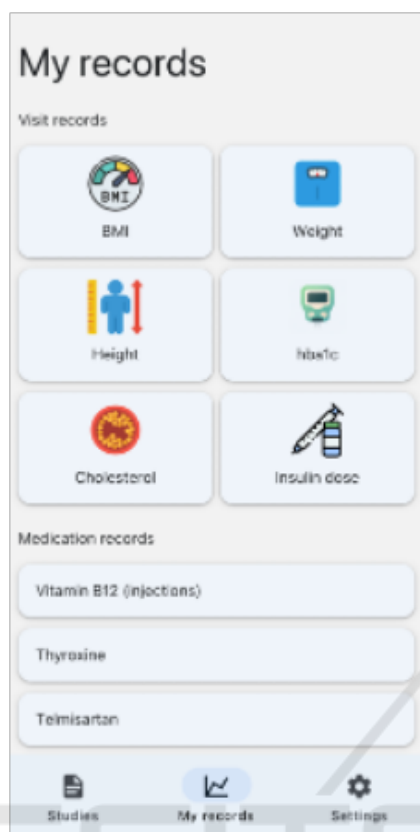


Figure 9: Augmented e-Consent workflow.

condition of GDPR consent, - for those patients who may opt against using the app - they can still request their data via traditional means through their clinicians. Furthermore, for those who use the app but decide not to provide specific consents to specific research project requests to use their data, the "My Records" dashboard remains accessible, ensuring they aren't disadvantaged or penalised for their choices.

The app itself requires a unique token to be generated on the server before it can be used. This is used for several purposes: to activate the mobile application; to identify the end user mobile application (and hence the anonymised patient) so that they can access and see their data and get notifications of studies related to the use of their data, and to encrypt the data sent between the mobile application and the server. It is important to note that all of the data within the ADDN data registry has been anonymised at source. The mobile application also has no uniquely identifying data that is kept. The web and mobile applications have been developed based on privacy by design principles. There is no need to know the specific individual details. Instead, all patients are associated with a unique and system-generated identifier on the server.

## 5 DISCUSSION

Our augmented workflow of e-Consent and the concrete example in the ADDN context offers practical guidance for other biomedical research registries aiming to comply with strict health data access regulations. However, some limitations must be acknowledged. There is no standard implementation for the consent application due to the multifaceted nature of biomedical research demands.

Data controllers still need to consider the specific requirements of their research registry when determining the most appropriate consent process. Two key factors to take into account are altruism and the stage of the research. For instance, the disease registry RUDY project (Rare UK Diseases of bone, joints and blood vessels) (Teare et al., 2017) project has demonstrated that patients with extensive experience of their disease can become active partners in research. (Garrison et al., 2016)(Spencer and Patel, 2019) also found that altruistic benefits of sharing health-related data sometimes outweighs the associated risks, leading participants to prefer broader consent or even full access (Wallace and Miola, 2021) in their efforts to contribute to society. The maturity of a given research registry and the level of trust established with its participants should also influence the introduction of new consent mechanisms. As highlighted by (Wallace and Miola, 2021) for mature registries where participants have developed trust in the project, introducing a new consent system may introduce risks and potentially jeopardize the relationship with participants instead of providing benefits. Therefore, the timing and manner of rolling out novel consent procedures need to be considered. Moreover, not all research registries might have the technological infrastructure or expertise to deploy such advanced e-Consent platforms. Indeed, this is one of the key factors that controllers should take into account.

Furthermore, data protection regulations are continuously evolving. In the Australian context, while our work is based on the latest government response, the Privacy Act 1988 is still under review. The final revised version has yet to be released. As such, there could be further discrepancies between the finalized version of this Act and GDPR with regards to consent conditions. Such disparities may necessitate further adjustments in the future.

## 6 CONCLUSIONS

In the evolving landscape of biomedical research, the move towards electronic informed consent (e-



Consent) is inevitable. The up-to-date review of e-consent by (Skelton et al., 2020) presented a workflow of the informed consent processes, but this was more theoretical than practical and did not consider evolving privacy mandates and the longitudinal nature of research data and evolving research demands. In this paper we explore the complexities of aligning e-Consent mechanisms with stringent global data protection regulations, notably GDPR.

Through the exploration of the biomedical research registry Australasian Diabetes Data Network's (ADDN)'s consent app, we illuminate practical implementations that adhere to such regulations while enhancing the patient experience.

We also presented an improved GDPR-compliant consent workflow in biomedical research settings. This provides guidance to other biomedical research registries attempting to navigate the complexities of GDPR-compliant e-consent implementations.

We note that the mobile application is undergoing advanced testing and will be rolled out as part of the ADDN project in due course. The adoption, use and feedback of the application will be explored in downstream work.

## ACKNOWLEDGEMENTS

The authors would like to thank the ADDN project partners for the ongoing work and support.

## REFERENCES

- Ausloos, J. (2012). The 'right to be forgotten' - worth remembering? *Computer Law and Security Review*, 28(2):143–152.
- Australian Government (2022). Privacy act review - discussion paper. Webpage. Accessed on 2023-11-29.
- Chimonas, S., Lipitz-Snyderman, A., Matsoukas, K., and Kuperman, G. (2023). Electronic consent in clinical care: an international scoping review. *BMJ Health & Care Informatics*, 30(1).
- Cohen, E., Byrom, B., Becher, A., Jörntén-Karlsson, M., and Mackenzie, A. K. (2023). Comparative effectiveness of econsent: Systematic review. *Journal of medical Internet research*, 25.
- Dankar, F. K., Gergely, M., Malin, B., Badji, R., Dankar, S. K., and Shuaib, K. (2020). Dynamic-informed consent: A potential solution for ethical dilemmas in population sequencing initiatives. *Comput Struct Biotechnol J*, 18:913–921.
- de Man, Y., Wieland-Jorna, Y., Torensma, B., de Wit, K., Francke, A. L., Oosterveld-Vlug, M. G., and Verheij, R. A. (2023). Opt-in and opt-out consent procedures

for the reuse of routinely recorded health data in scientific research and their consequences for consent rate and consent bias: Systematic review. *Journal of medical Internet research*, 25.

- De Sutter, E., Zaçe, D., Boccia, S., Di Pietro, M. L., Geerts, D., Borry, P., and Huys, I. (2020). Implementation of electronic informed consent in biomedical research and stakeholders' perspectives: systematic review. *Journal of medical Internet research*, 22(10).
- Del Carmen, M. G. and Joffe, S. (2005). Informed consent for medical treatment and research: a review. *The oncologist*, 10(8):636–641.
- Garrison, N. A., Sathe, N. A., Antommaria, A. H. M., Holm, I. A., Sanderson, S. C., Smith, M. E., McPheeters, M. L., and Clayton, E. W. (2016). A systematic literature review of individuals' perspectives on broad consent and data sharing in the united states. *Genetics in Medicine*, 18(7):663–671.
- Haas, M. A., Teare, H., Prictor, M., Ceregra, G., Vidgen, M. E., Bunker, D., Kaye, J., and Boughtwood, T. (2021). 'ctrl': an online, dynamic consent and participant engagement platform working towards solving the complexities of consent in genomic research. *Eur J Hum Genet*, 29(4):687–698.
- Hewitt, R. and Watson, P. (2013). Defining biobank. *Biopreservation and biobanking*, 11(5):309–315.
- Holm, S. and Ploug, T. (2017). Big data and health research—the governance challenges in a mixed data economy. *Journal of bioethical inquiry*, 14:515–525.
- Kaye, J., Whitley, E. A., Lund, D., Morrison, M., Teare, H., and Melham, K. (2015). Dynamic consent: a patient interface for twenty-first-century research networks. *Eur J Hum Genet*, 23(2):141–146.
- Lee, H. and Lee, U. (2022). Toward dynamic consent for privacy-aware pervasive health and well-being: A scoping review and research directions. *IEEE Pervasive Computing*.
- Mamo, N., Martin, G. M., Desira, M., Ellul, B., and Ebejer, J. P. (2020). Dwarna: a blockchain solution for dynamic consent in biobanking. *Eur J Hum Genet*, 28(5):609–626.
- Mascalzoni, D., Melotti, R., Pattaro, C., Pramstaller, P. P., Gögele, M., De Grandi, A., and Biasiotto, R. (2022). Ten years of dynamic consent in the chris study: informed consent as a dynamic process. *Eur J Hum Genet*, 30(12):1391–1397.
- Mirza, A. B., Khoja, A. K., Ali, F., El-Sheikh, M., Bibi-Shahid, A., Trindade, J., Rocos, B., Grahovac, G., Bull, J., and Montgomery, A. (2023). The use of e-consent in surgery and application to neurosurgery: a systematic review and meta-analysis. *Acta Neurochirurgica*, pages 1–32.
- Ploug, T. and Holm, S. (2015). Meta consent: a flexible and autonomous way of obtaining informed consent for secondary research. *BMJ*, 350:h2146.
- Skelton, E., Drey, N., Rutherford, M., Ayers, S., and Malamateniou, C. (2020). Electronic consenting for conducting research remotely: A review of current practice and key recommendations for using econsent

- ing. *International Journal of Medical Informatics*, 143:104271–104271.
- Spencer, A. and Patel, S. (2019). Applying the data protection act 2018 and general data protection regulation principles in healthcare settings. *Nursing Management*, 26(1).
- Sugarman, J., McCrory, D. C., and Hubal, R. C. (1998). Getting meaningful informed consent from older adults: a structured literature review of empirical research. *Journal of the American Geriatrics Society*, 46(4):517–524.
- Teare, H. J. A., Hogg, J., Kaye, J., Luqmani, R., Rush, E., Turner, A., Watts, L., Williams, M., and Javaid, M. K. (2017). The rudy study: using digital technologies to enable a research partnership. *Eur J Hum Genet*, 25(7):816–822.
- Wallace, S. E. and Miola, J. (2021). Adding dynamic consent to a longitudinal cohort study: A qualitative study of exceed participant perspectives. *BMC Med Ethics*, 22(1):12.
- Wang, Z., Stell, A., Sinnott, R. O., and Group, A. S. (2022). The impact of general data protection regulation on the australasian type-1 diabetes platform. pages 21–23 July 2022.
- Wang, Z., Stell, A., Sinnott, R. O., and The Addn Study, G. A gdpr-compliant dynamic consent mobile application for the australasian type-1 diabetes data network. *Healthcare (Basel)*, 11(4).
- Williams, H., Spencer, K., Sanders, C., Lund, D., Whitley, E. A., Kaye, J., and Dixon, W. G. (2015). Dynamic consent: A possible solution to improve patient confidence and trust in how electronic patient records are used in medical research. *JMIR Med Inform*, 3(1):e3.
- Win, K. T. and Fulcher, J. A. (2007). Consent mechanisms for electronic health record systems: a simple yet unresolved issue. *Journal of Medical Systems*, 31:91–96.

## APPENDIX

Table 1: Specific consent requirements associated with the five GDPR conditions based on the augmented e-Consent workflow.

Consent Condition	Requirement	App Interface	Example
Freely Given	Consent should be given without any pressure, ensuring no imbalance between the data subject and controller.	The first screenshot (a) of the ADDN app shows a dashboard with a list of studies. When new studies are approved by the ADDN study group, they are displayed here for targeted participants. Each study's entry acts as an invitation, not a command.	The BMI study appears on the dashboard without any highlighting or prioritization, ensuring users don't feel compelled to participate.
Specific	Consent must be collected for distinct, predefined purposes.	By selecting a study from the dashboard, like the BMI study, users are taken to (b), which offers detailed information about the specific study, ensuring the user knows precisely what they are consenting to.	The BMI study information clearly outlines the specific goals and purposes of the study, and details how the specific data will be collected and utilised.
Informed	Data subjects should fully understand the data processing activities and any associated implications.	(b) offers study details and provides a direct link to the (c), allowing users to view the exact data records that will be used for the study.	For the BMI study, users can view their BMI data, ensuring they're completely aware of what information is being used.
Unambiguous & Opt-in	It should be crystal clear whether a user has given their consent. GDPR demands an explicit opt-in system.	Within the detailed study page (b), users have the explicit choice to 'Consent' or 'Withdraw'. Only an active action (like pressing 'Consent') will register as the user giving their permission.	If a user decides to consent to the BMI study, the user has to press the 'Consent' button; otherwise, the consent is not given, and ADDN can't use the data.
Ease of Withdrawal	Withdrawing consent should be as simple as giving it. Upon withdrawal, their data should be removed from the study.	The 'Withdraw' option on the detailed study page (a) ensures that users can pull back their consent at any time, and it will be as easy as giving the consent.	If a user initially agrees to the BMI study but later decides against it, they can simply press 'Withdraw', and their BMI data will not be used, but they can still consent to other studies.
Right to be Forgotten	Users should have the power to request that all their data be deleted from the ADDN platform permanently, reflecting the GDPR's "Right to be Forgotten."	A 'Delete My Data' button (d) lets users remove all their data from ADDN, withdrawing from all studies and permanently erasing their presence on the platform.	If a user decides to exit the ADDN platform entirely, they can press 'Delete My Data', wiping out all their records and simultaneously revoking consent for all studies they had previously agreed to.