SUBMISSION

Submission: Review of PD2010_055 — Section 4.6, Universal Consent for Use of Patient Data in Research

Submitted to: Office for Health and Medical Research (OHMR), NSW Health

In response to: *Discussion Paper – PD2010_055: Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations*, Section 4.6

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Introduction

We welcome the opportunity to respond to Section 4.6 of the Discussion Paper on universal or broader consent for the use of patient data in research. We are academic researchers with expertise in health law, research ethics, and consent for people who face barriers to giving study-specific consent, including through progressive loss of decision-making capacity.

Our core submission is that **a broad consent model should be understood and designed as a form of advance research planning, rather than a one-off administrative event.** Our recommendations draw on our program of empirical and legal research on advance planning for research.

Advance research planning (ARP) is a process by which people think about, discuss and document their preferences for taking part in research during future periods of impaired decision-making capacity. The process typically involves preparing an **advance research directive** (ARD), a document that records a person's wishes about future research participation, the types of research they would or would not want to be involved in, and may also nominate a trusted person to be involved in future decisions about research involvement. An example of an ARD template is here: https://www.stepupfordementiaresearch.org.au/useful-resources-2/.

The key principles for ARP – including genuine understanding about options, ongoing communication, clear legal status of advance choices, and options to update preferences or withdraw – should underpin any model of broader consent that NSW Health may adopt.

Response to Question 1, What role, if any, should universal or broader consent models play in supporting research use of patient data within NSW Health?

There are legitimate arguments for adopting some form of broader consent. As the Discussion Paper notes, repeated study-specific consent is increasingly impracticable for large scale, longitudinal and data linkage research. The appropriateness and feasibility of any broader consent model depends on how it is designed, communicated and governed.

We recommend that any such model enables a **considered planning process**, rather than a system-entry tick-box. This means:

- clear, accessible information about what future research can and cannot mean;
- a genuine opportunity to ask questions and decline or limit participation by category rather than only a broad yes/no;
- clear points at which the person can revisit the decision.

While some people may be agreeable to a universal consent approach, we recommend that the model should offer some degree of choice around the scope of consent given. For example, this could include categories including: field of study; disease area; type of data; and commercial or non-commercial use. This is similar to the NSW Health InFORMed Patient Information and Consent Form template. We recommend NSW Health pilot test a set of preference options to determine a suitable number and definition of categories that enable some choice while remaining feasible for data extraction processes.

Response to Question 2, What safeguards, mechanisms or transparency measures would be necessary to support public trust in a universal consent approach?

Human Research Ethics Committee (HREC) Review. HREC review of research using broadly consented data should be required, particularly given that the original consent could not contemplate a specific future project. This safeguard is consistent with national ethics guidelines and international recommendations that broad consent approaches be accompanied by ongoing oversight (see e.g., Thorogood et al., 2018).

Open and ongoing communication. Maintaining public trust in a universal or broader consent model requires transparency as to who is able to request access to patient data and for what kinds of purposes. Communication with the public should be ongoing and provide opportunities for engagement, both to make consent decisions about one's own patient data and to have input on future developments (e.g., in relation to artificial intelligence, data and privacy). We recommend co-production of informational materials with patient and community representatives. Much of the evidence base and recommendations on informed consent has been shaped by researcher and clinician perspectives, with comparatively less input from people with lived/living experience (see e.g., Diaz et al., 2025). Consumer involvement, including with a diverse range of communities, should be a central feature in the design and implementation of a universal or broader consent model.

Legal status of stated preferences. The status of stated preferences should be clear and explained; for example, are they binding or advisory. In our research on ARDs, nearly half of participants believed an ARD should be legally enforceable, while others saw it as a non-binding document to guide decisions about their participation in research (Ries & Johnston, 2023). Recognising that community views are likely mixed, NSW Health should state a clear policy position and communicate it openly. It should also be clear who may act on a person's behalf in research decisions, such as the legal authority of an enduring guardian (see further comments below on capacity considerations).

Response to Question 3, What practical considerations should NSW Health take into account when assessing the appropriateness of implementing a universal or broader consent model (e.g. communication with patients, withdrawal processes, system capability)?

Offering and operationalising preferences. As noted above, we recommend offering a set of preference options that are clear and understandable. The system must then check and follow recorded preferences before extracting or pooling data.

Withdrawal and updating preferences. People must be able to withdraw consent or update a previously given scope of consent. Such process should be accessible and low-burden, including paper options to avoid digital inequity. Information should also be available about any data already used in completed or in-progress projects.

Capacity considerations. The model should address both people who lack capacity at system entry and people whose capacity changes after giving consent. The importance of periodically reviewing preferences and accommodating changes over time — particularly as circumstances change following a loss of capacity — has been highlighted across multiple studies (Shepherd & Ries, 2026). The UK-based CONSULT research programme's work on advance research planning is directly relevant, exploring the acceptability and feasibility of advance research planning to enable people to express preferences about research participation during future periods of incapacity (Shepherd, Hood & Wood, 2024). This work highlights the importance of encouraging people to discuss their research preferences with those who would be involved in research decisions, rather than relying on documentation alone, and the need for tailored information and resources for all groups involved (e.g patients, appointed enduring guardians, family members, HRECs, researchers). The legal authority of substitute decision-makers should be clear, including their authority to make initial consent decisions at system entry and to subsequently update or withdraw consent on behalf of a person who lacks decisional capacity.

Summary recommendations

1. Model universal or broader consent as an advance research planning process, not a one-off administrative event.
2. Require HREC review for research using universally or broadly consented data.
3. Mandate transparent disclosure of who can access data and for what purposes.
4. Offer a fixed set of preference categories, developed through pilot testing. Resource the infrastructure needed to check and adhere to individual preferences before data extraction/pooling.
5. Clarify the legal status (binding vs advisory) of consent preferences, as well as who may act as a substitute decision-maker in research decisions.
6. Provide accessible, low-burden withdrawal and preference update mechanisms. Ensure non-digital consent and withdrawal channels for digital equity.
7. Invest in ongoing, co-produced communication and community engagement, including people with lived/living experience.

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