10

Consent

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10.1 INTRODUCTION

Informed consent is regarded as the cornerstone of medical research; a mechanism that respects human dignity and enables research participants to exercise their autonomy and self-determination. It is a widely accepted legal, ethical and regulatory requirement for most health research. Nonetheless, the practice of informed consent varies by context, is subject to exceptions, and, in reality, often falls short of the theoretical ideal.[1] The widespread use of digital technologies this century has revolutionised the collection, management and analysis of data for health research, and has also challenged fundamental principles such as informed consent. The previously clear boundaries between health research and clinical care are becoming blurred in practice, with implications for implementation and regulation. Through our analysis we have identified the key components of consent for research articulated consistently in international legal instruments. This chapter will: (1) describe the new uses of data and other changes in health research; (2) discuss the legal requirements for informed consent for research found in international instruments; and (3) discuss the challenges in meeting these requirements in the context of emerging research data practices.

10.2 THE CHANGING NATURE OF RESEARCH

Health research is no longer a case simply of the physical measurement and intimate observation of patients. Rather, it increasingly depends upon the generation and use of data, and new analysis tools such as Artificial Intelligence (AI). Health research has been transformed by innovations in digital technologies enabling the collection, curation and management of large quantities of diverse data from multiple sources. The intangible nature of digital data means that it can be perfectly replicated indefinitely, instantly shared with others across geographical borders and used for multiple purposes, such as clinical care and research. The information revolution enables data to be pulled from different sources such as electronic medical records; wearables and smart phones monitoring chronic conditions; and datasets outside the health care system yielding inferences about an individual's health. These developments have significant implications for informed consent.

[1] C. Grady, 'Enduring and Emerging Challenges of Informed Consent', (2015) *New England Journal of Medicine*, 372(9), 855–862.

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New technologies have enabled the development of ambitious scientific agendas, new types of infrastructure such as biobanks and genomic sequencing platforms and international collaborations involving datasets of thousands of research participants. Much innovation is driven by collaborations between clinical and research partners that provide practical need and clinical data, and companies offering technical expertise and resources. Examples are: national genomic initiatives including Genomics England (UK), All of Us (USA), Aviesan (France), Precision Medicine Initiative (China); international research collaborations like the Human Genome Project, Global Alliance for Genomics and Health, the Personal Genome Project; and mission-orientated collaborations such as Digital Technology Supercluster (Canada) and the UK Health Data Research Alliance.

The greatest challenges emerge around informed consent in these new contexts where already-collected data can be used in ways not anticipated at the time of collection and data can be sent across jurisdictional borders. When data and tissue samples are being collected for multiple unknown future research uses, explicit informed consent to the research aims and methods may not be possible. In response to this practical challenge, the World Medical Association (WMA) adopted the *Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks* (2002, revised 2016). It stipulates that instead of consenting to individual research, individuals may validly consent to the purpose of the biobank, the governance arrangements, privacy protections, risks associated with their contribution and so on. This form of 'broad consent' is really an agreement that others will govern the research, since determinations about appropriate uses of the data and biomaterials are decided by researchers with approval by research ethics committees or similar bodies.[2]

10.3 THE BASIS FOR INFORMED CONSENT

The moral force of consent is not unique to health research; it is integral to many interpersonal interactions, as well as being entrenched in societal values. The key moral values at play in medical research are: **autonomy** – the right for an individual to make his or her own choice; **beneficence** – the principle of acting with the participant's best interests in mind; **non-maleficence** – the principle that 'above all, do no harm'; and **justice** – emphasising fairness and equality among individuals.[3] The concepts of voluntariness and transparency embedded in informed consent speak to the ethical value of respect for human beings, their autonomy, their dignity as free moral agents and their welfare. This respect for individuals has resulted in special protections for those who are not legally competent to provide informed consent. Beneficence requires that the probable benefits of the research project outweigh the harms. In the context of informed consent, non-maleficence demands that harm is minimised by researchers being attuned to participant welfare and fully disclosing likely benefits and risks to permit adequately informed choice. The principle of justice in the research setting requires that potential participants are equally provided with adequate information to make a knowledgeable decision, helping to avoid participant exploitation. Consideration of the ethical principles underpinning informed consent also requires reflection on cultural values, such as those pertaining to specific indigenous communities or ethnic groups. Cultural values may lead researchers to consider, for example, whether unique harms to cultural integrity and heritage could accrue to certain groups through specific research projects, and whether respect for human beings should be seen

[2] S. Boers et al., 'Broad Consent Is Consent for Governance', (2015) *American Journal of Bioethics*, 15(9), 53–55.
[3] T. Beauchamp and J. Childress, *Principles of Biomedical Ethics*, 4th Edition (Oxford University Press, 1994).

through a lens of collective, as well as individual, autonomy and well-being.[4] These ethical principles underpin informed consent in health research practice, but not all of them have been implemented into law.

10.4 LEGAL REQUIREMENTS FOR INFORMED CONSENT

The requirements for informed consent emerged from a range of egregious examples of physical experimentation on humans. Among the most notable examples were the Nuremberg trials following World War II, although concern about harmful research practices internationally had surfaced decades earlier.[5] The trial of Nazi doctors produced a ten-point Code that became the foundation of modern health research ethics. Voluntary consent was its first and arguably most emphasised principle.[6] It has since been espoused in declarations by international and non-governmental organisations. A key instrument is the WMA's Declaration of Helsinki (1964, as amended) setting out the basic requirements for informed consent for research.

> In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.[7]

Crucial to this formulation is the need to communicate and provide detailed information to the 'human subject'. While this information should be comprehensive enough for participants to make an informed decision, it positions the researcher as the information provider and the subject as a passive recipient. Yet, the Declaration also posits ongoing engagement as an essential requirement as the participant can withdraw consent at any time.

The principle of free consent also forms part of the United Nations' International Covenant on Civil and Political Rights (Article 7). Further guidelines and conventions promulgated by international organisations such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH),[8] the Council for International Organizations of Medical Sciences,[9] and the Council of Europe,[10] endorse and explain these principles. The ICH Good Clinical Practice Guideline considers consent in the context of human clinical trials; it establishes a unified quality standard for the European Union, Japan and

[4] For instance: National Health and Medical Research Council [Australia], 'Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities', (NHMRC, 2018); L. Jamieson et al., 'Ten Principles Relevant to Health Research among Indigenous Australian Populations', (2012) *Medical Journal of Australia*, 197(1), 16–18.

[5] A. Dhai, 'The Research Ethics Evolution: From Nuremberg to Helsinki', (2014) *South African Medical Journal*, 104 (3), 178–180.

[6] Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 [Nuremberg Code] (1949) para. 1.

[7] World Medical Association, 'Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects', (World Medical Association, 1964, 2013 version), para. 26. [hereafter 'Declaration of Helsinki']

[8] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), 'Guideline for Good Clinical Practice', (ICH, 1996).

[9] Council for International Organizations of Medical Sciences, 'International Ethical Guidelines for Biomedical Research Involving Human Subjects', (CIOMS, 2002, updated 2016).

[10] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 04/04/1997, in force 01/12/1999, ETS No. 164.

the USA. The Oviedo Convention and the 2005 Additional Protocol relating to biomedical research similarly foreground consent, stipulating that it be 'informed, free, express, specific and documented'.[11] The European General Data Protection Regulation (GDPR) has raised the bar for informed consent for data use worldwide. In Australia, the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* (2007, updated 2018) is the principle guiding document for health research. From these documents, several key components can be discerned, such as competence, transparency and voluntariness, and that consent must be informed.

Only 'human subjects capable of giving informed consent' are the subject of the Helsinki Declaration statement about consent. Ethicists have described competent people as those who have 'the capacity to understand the material information, to make a judgement about the information in light of his or her values, to intend a certain outcome, and to freely communicate his or her wish to caregivers or investigators'.[12] Special protections pertain to those not competent to give consent, such as some young children and some people who are physically, mentally or intellectually incapacitated. These protections centre upon authorisation by a research ethics committee and consent provided by a legal representative. The potential participant may still be asked to assent to the research.

Assessing competence represents a challenge in relation to biobanks and other longitudinal research endeavours where people contributing data or tissue samples may have shifting competence over time; for instance people who were enrolled into research as children will become competent to provide consent for themselves as they reach adulthood.[13] People impacted by cognitive decline or mental illness may lose competence to provide consent, either temporarily or indefinitely. Periodically revisiting consent for participants is an ethically appropriate, yet logistically demanding, response.

As indicated above, the Nuremberg Code and the Declaration of Helsinki outline a range of information that potential research participants are to be given to enable them to be informed before making a choice about enrolment. The ICH Guideline goes into further detail regarding clinical trials, stating that the information should be conveyed orally and in writing (4.8.10), and that that the explanation should include:

- Whether the expected benefits of the research pertain to the individual participants;
- What compensation is available if harm results;
- The extent to which the participant's identity will be disclosed;
- The expected duration of participation;
- How many participants are likely to be involved in the research.

National or regional statutes and guidelines stipulate the required informational elements for consent to health research in their jurisdictions, mirroring the elements contained in the international instruments to varying degrees.[14]

[11] Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research,' Strasbourg, 21/05/2005, in force 01/09/2007, CETS No. 195, Article 14.1.

[12] Beauchamp and Childress, *Principles of Biomedical Ethics*, p. 135.

[13] M. Taylor et al., 'When Can the Child Speak for Herself?', (2018) *Medical Law Review*, 26(3), 369–391.

[14] For example, Human Biomedical Research Act 2015, sec. 12 (Singapore); National Health and Medical Research Council, Australian Research Council, and Universities Australia, 'National Statement on Ethical Conduct in Human Research', (NHMRC, 2007), ch 2.2. [hereafter 'NHMRC National Statement']; Health Research Authority, 'Consent and Participant Information Guidance', (HRA) (UK) ; Federal Policy for the Protection of Human Subjects ('Common Rule'), 45 CFR part 46, para. 46.114, (1991); The Medicines for Human Use (Clinical Trials) Regulations 2004 No. 1031, Schedule 1 (UK).

Limited disclosure of information may sometimes be permitted, for instance in a study of human behaviour where the research aims would be frustrated by full disclosure to participants.[15] It may also be a necessary consequence of the difficulty of comprehensive disclosure in the context of Big Data science, where not all the uses of the data (that may not be collected directly from the individual) can be anticipated when the data are collected.

The Declaration of Helsinki requirement that research participants must be 'adequately informed' points to further consideration of how best to communicate the complex information described above. This is the focus of much recent law and guidance.[16] Research has shown repeatedly that participants often do not understand the investigative purpose of clinical trials, key concepts such as randomisation and the risks and benefits of participation.[17] Using simple language and providing enough time to consider the information can help, as well as tailoring information to participant age and educational level. Researchers have evaluated tools to assist with communicating information in ways that support understanding.[18] Complex, heterogenous and changing research endeavours that cross geographic boundaries and blur the lines between clinical care, daily life and research pose an additional challenge to the requirement for transparency.

A consistent requirement of international conventions, law and guidelines for ethical research is that for consent to be valid, it must be voluntary.[19] The Nuremberg Code obliges researchers to avoid 'any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion'.[20] Beyond the problem of overt coercion by another person, other considerations in evaluating voluntariness include: deference to the perceived power of the researcher or institution;[21] the mere existence of a power imbalance;[22] the existence of a dependent relationship with the researcher;[23] and the amount paid to participants.[24] On power and vulnerabilities, see further Brassington, Chapter 9, this volume.

These concerns are largely associated with duress as a result of specific relationships developed through personal interactions. In Big Data or AI analysis, the concept of voluntariness must be reconsidered, as often the data users are not known to the data subject and the nature of the duress may not be straightforwardly attributed to particular relationships. An example is companies that provide direct-to-consumer genetic tests, where the provision of test results also enables the companies to use the data for purposes including marketing and research. This is a

[15] NHMRC National Statement, chap. 2.3.

[16] NHMRC National Statement, para. 5.2.17; Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1 Recital 58.

[17] M. Falagas et al., 'Informed Consent: How Much and What Do Patients Understand?', (2009) *American Journal of Surgery*, 198(3), 420–435; On risk-benefit analysis, see also Coleman, Chapter 13 in this volume.

[18] For example: A. Synnot et al., 'Audio-Visual Presentation of Information for Informed Consent for Participation in Clinical Trials', (2014) *Cochrane Database of Systematic Reviews*, (5); J. Flory and E. Emanuel, 'Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review', (2004) *JAMA*, 292(13), 1593–1601.

[19] Additional Protocol to the Convention on Human rights and Biomedicine, Article 14.1; ICH, 'Guideline for Good Clinical Practice', paras 2.9 and 3.1.8; NHMRC National Statement, para. 2.2.9; General Data Protection Regulation, Article 4(11); Declaration of Helsinki, para. 25.

[20] Nuremberg Code, para. 1.

[21] NHMRC National Statement, para. 2.2.9.

[22] General Data Protection Regulation, Recital 43.

[23] Declaration of Helsinki, para. 27.

[24] ICH, 'Guideline for Good Clinical Practice', para. 3.1.8; NHMRC National Statement, para. 2.2.10.

different kind of duress as people lured through the fine print in click-wrap contracts are then enrolled into research.[25]

Traditionally, valid informed consent occurs before the participant's involvement in the research;[26] no specific timing is recommended as long as there is time for the person to acquire sufficient understanding of the research. In selected circumstances, 'deferred' consent – where individuals do not know they are enrolled in a clinical trial so that the sample is not biased and they are asked for consent later on[27] – a waiver of consent or an opt-out approach might be justifiable. These are typically addressed within relevant guidance.[28] Once-off informed consent before a project starts may, however, be insufficient to acquit researchers' responsibilities in the context of longitudinal data-intense research infrastructures. Modalities that permit ongoing or at least repeated opportunities to refresh consent, such as staged consent and Dynamic Consent, considered below, are a developing response to this issue.

It is a key principle of health research, traceable back to the Declaration of Helsinki, that potential research participants have a right to decline the invitation to participate without giving a reason and should not incur any disadvantage or discrimination as a consequence.[29] Further, people who have consented must be free to withdraw consent at any time without incurring disadvantage. The GDPR stipulation that 'It shall be as easy to withdraw as to give consent',[30] has energised research into technology-based tools to facilitate seamless execution of a withdrawal decision, or even to support shifting levels of participation over time.[31]

Newer research methods and infrastructures characterised by open-ended research activities and widespread data sharing add complexity to the interpretation of 'withdrawing consent'. International guidelines have acknowledged that withdrawal in this context might equate to no new data collection while raising a question over whether existing samples and data must be destroyed or remain available for research.[32]

10.5 THE LIMITATIONS OF CONSENT

In research involving human participants, the informed consent process is foregrounded.

As a legal mechanism intended to protect human subjects in the way envisaged by international instruments, it is also recognised that consent may be insufficient. People often do not understand what they have agreed to participate in, retain the information about the research or even recall that they agreed to be involved.[33] Consent is not the only legal basis for conducting

[25] A. Phillips, *Buying your Self on the Internet: Wrap Contracts and Personal Genomics* (Edinburgh University Press, 2019).

[26] ICH, 'Guideline for Good Clinical Practice', para. 2.9.

[27] L. Johnson and S. Rangaswamy, 'Use of Deferred Consent for Enrolment in Trials is Fraught with Problems', (2015) *BMJ*, 351.

[28] NHMRC National Statement, chap. 2.3; The paper N. Songstad et al. and on behalf of the HIPSTER trial investigators, 'Retrospective Consent in a Neonatal Randomized Controlled Trial', (2018) *Pediatrics*, 141(1), e20172092 presents an example of deferred consent.

[29] Declaration of Helsinki, paras 26, 31.

[30] General Data Protection Regulation, Article 7(3).

[31] K. Melham et al., 'The Evolution of Withdrawal: Negotiating Research Relationships in Biobanking' (2014) *Life Sciences, Society and Policy*, 10(1), 1–13.

[32] Council for International Organizations of Medical Sciences and World Health Organization, 'International Ethical Guidelines for Epidemiological Studies', (CIOMS, 2009) p. 48.

[33] J. Sugarman et al., 'Getting Meaningful Informed Consent From Older Adults: A Structured Literature Review of Empirical Research', (1998) *Journal of the American Geriatrics Society*, 46(4), 517–524; P. Fortun et al., 'Recall of Informed Consent Information by Healthy Volunteers in Clinical Trials', (2008) *QJM: An International Journal of Medicine*, 101(8) 625–629; R. Broekstra et al., 'Written Informed Consent in Health Research Is Outdated', (2017)

health research. While there is variation between jurisdictions, broadly speaking research involving data or tissue may be able to proceed without consent in certain circumstances. These include if: there is an overriding public interest and consent is impracticable; there is a serious public health threat; the participant is not reasonably identifiable; or the research carries low or negligible risk. Many researchers have sought to augment traditional modes of consent at the point of entry to research, to support informed decision-making by potential participants. New consent processes seek to enable truly informed consent rather than doing away with this fundamental requirement.

Traditionally, consent is operationalised as a written document prepared by the researcher setting out the information described above. The participant's agreement is indicated by their signature and date on the document. Concerns about participant problems with reading and understanding the form have led to initiatives including simplified written materials, extra time and the incorporation of multimedia tools.[34] More nuanced consent modalities might encompass different tiers of information – with simple, minimally compliant information presented first, linking to more comprehensive explanation – and different staging of information, for instance with new choices being presented to participants at a later time.[35]

Scholars have also considered when and how it might be appropriate to diverge from the notion of the individual human subject as the autonomous decision-maker for health research participation, towards a communitarian approach informed by ethical considerations pertaining to culture and relationships. The concept of informed consent must, in this context, expand to incorporate the possibility of family and community members at least being consulted, perhaps even deciding jointly. Osuji's work on relational autonomy in informed consent points to decisions 'made not just in relation to others but with them, that is, involving them: family members, friends, relations, and others'.[36] This approach might particularly suit some groups, with extensive examples deriving from Australian aboriginal and other Indigenous communities,[37] family members with shared genetic heritage[38] and some Asian and African cultures.[39] Communitarian-based consent processes may not meet legal requirements for informed consent to research, but may nevertheless be a beneficial adjunct to standard processes in some instances.

European Journal of Public Health, 27(2), 194–195; Falagas et al., 'Informed Consent'; H. Teare et al., 'Towards "Engagement 2.0": Insights From a Study of Dynamic Consent with Biobank Participants', (2015) *Digital Health*, 1, 1–13.

[34] A. Nishimura et al., 'Improving Understanding in the Research Informed Consent Process', (2013) *BMC Medical Ethics*, 14(1), 1–15; Synnot et al., 'Audio-Visual Presentation'; B. Palmer et al., 'Effectiveness of Multimedia Aids to Enhance Comprehension of Research Consent Information: A Systematic Review', (2012) *IRB: Ethics & Human Research*, 34(6), 1–15; S. McGraw et al., 'Clarity and Appeal of a Multimedia Informed Consent Tool for Biobanking', (2012) *IRB: Ethics & Human Research*, 34(1), 9–19; C. Simon et al., 'Interactive Multimedia Consent for Biobanking: A Randomized Trial', (2016) *Genetics in Medicine*, 18(1), 57–64.

[35] E. Bunnik et al., 'A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing', (2013) *European Journal of Human Genetics*, 21(6), 596–601.

[36] P. Osuji, 'Relational Autonomy in Informed Consent (RAIC) as an Ethics of Care Approach to the Concept of Informed Consent', (2017) *Medicine, Health Care and Philosophy*, 21(1), 101–111, 109.

[37] F. Russell et al., 'A Pilot Study of the Quality of Informed Consent Materials for Aboriginal Participants in Clinical Trials', (2005) *Journal of Medical Ethics*, 31(8), 490–494; P. McGrath and E. Phillips, 'Western Notions of Informed Consent and Indigenous Cultures: Australian Findings at the Interface', (2008) *Journal of Bioethical Inquiry*, 5(1), 21–31.

[38] J. Minari et al., 'The Emerging Need for Family-Centric Initiatives for Obtaining Consent in Personal Genome Research', (2014) *Genome Medicine*, 6(12), 118.

[39] H3Africa Working Group on Ethics, 'Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa', (H3Africa, 2017).

10.6 NEW DIGITAL CONSENT MECHANISMS

The pervasion of technology into all aspects of human endeavour has transformed health research activities and the consent processes which support them. Electronic consent may mean simply transferring the paper form to a computerised version. Internationally, electronic signatures are becoming generally accepted as legally valid in various contexts.[40] These may comprise typewritten or handwritten signatures on an electronic form, digital representations such as fingerprints or cryptographic signatures. Progress is being made on so-called digital, qualified or advanced electronic signatures which can authenticate the identity of the person signing, as well as the date and location.[41]

Semi-autonomous consent is emerging in computer science; it refers to an approach in which participants record their consent preferences up-front, a computer enacts these preferences in response to requests – for instance, invitations to participate in research – and the participants review the decisions, refine their expressed preferences and provide additional information.[42] This could be a way to address consent fatigue by freeing participants from the need to make numerous disaggregated consent decisions. It is a promising development at a time when increasing uses of people's health data for research may overwhelm traditional tick-box consent.

Dynamic Consent is an approach to consent developed to accommodate the changes in the way that medical research is conducted. It is a personalised, digital communication interface that connects researchers and participants, placing participants at the heart of decision-making. The interface facilitates two-way communication to stimulate a more engaged, informed and scientifically-literate participant population where individuals can tailor and manage their own consent preferences.[43] In this way it meets many of the requirements of informed consent as stipulated in legal instruments[44] but also allows for the complexity of data flows characterising health research and clinical care. The approach has been used in the PEER project,[45] CHRIS,[46] the Australian Genomics Health Alliance[47] and the RUDY project.[48] It seems appropriate to have digital consent forms for a digital world that allow for greater flexibility and engagement with patients when the uses of data for research purposes cannot be predicted at the time of collection.

[40] United Nations, 'United Nations Convention on the Use of Electronic Communications in International Contracts', (UNCITRAL, 2005) Article 9(3); Electronic Transactions Act 1999 (Cth) sec. 8(1); Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (2014); CFR Code of Federal Regulations Title 21 Part 11, (1997) (USA); Electronic Signatures in Global and National Commerce Act 2000, Pub. L. No. 106-229, 114 Stat. 464 (2000) (USA).

[41] Health Research Authority and Medicines and Healthcare Products Regulatory Agency, 'Joint Statement on Seeking Consent by Electronic Means', (HRA and MHPRA, 2018) p. 5.

[42] R. Gomer et al., 'Consenting Agents: Semi-Autonomous Interactions for Ubiquitous Consent', Proceedings of the 2014 ACM International Joint Conference on Pervasive and Ubiquitous Computing (Seattle, Washington: ACM Press, 2014), pp. 653–58.

[43] J. Kaye et al., 'Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks', (2015) *European Journal of Human Genetics*, 23, 141–146.

[44] M. Prictor et al. 'Consent for Data Processing Under the General Data Protection Regulation: Could "Dynamic Consent" be a Useful Tool for Researchers?', (2019) *Journal of Data Protection and Privacy*, 3(1), 93–112.

[45] Genetic Alliance, 'Platform for Engaging Everyone Responsibly', www.geneticalliance.org/programs/biotrust/peer.

[46] CHRIS eurac research, 'Welcome to the CHRIS study!', (CHRIS), www.de.chris.eurac.edu.

[47] Australian Genomics Health Alliance, 'Introducing CTRL', www.australiangenomics.org.au/introducing-ctrl-a-new-online-research-consent-and-engagement-platform.

[48] H. Teare et al., 'The RUDY Study: Using Digital Technologies to Enable a Research Partnership', (2017) *European Journal of Human Genetics*, 25, 816–822.

10.7 CONCLUSION

The organisation and execution of health research has undergone considerable change due to technological innovations that have escalated in the twenty-first century. Despite this, the requirements of informed consent enshrined in the Nuremberg Code are still the basic standard for health research. These requirements were formulated specifically in response to atrocities that occurred through physical experimentation. They continue to be applied to data-based research that is very different in its scope and nature, and in the issues it raises for individuals compared to physically-based research, that was the template for the consent requirements found in international instruments. The process for obtaining and recording consent has undergone little change over time and is still recorded through paper-based systems, reliant on one-to-one interactions. While this works well for single projects with a focus on the prevention of physical, rather than informational harm, it is less suitable when data are used in multiple settings for diverse purposes.

Paper-based systems are not flexible and responsive and cannot provide people with the information that is needed in a changing research environment. Digital systems such as Dynamic Consent provide the tools for people to be given information as the research evolves and to be able to change their mind and withdraw their consent. However, given the complexity and scale of research, when data are collected from a number of remote data points it is difficult for consent to effectively respond to all of the issues associated with data-intensive research. The use of collective datasets that concern communal or public interests are difficult to govern through individual decision-making mechanisms such as consent.[49]

Consent is only one of the many governance mechanisms that should be brought into play to protect people involved in health research. Additionally, attention should be given to the ecosystem of research and informational governance that consist of legal requirements, regulatory bodies and best practice that provide the protective framework that is wrapped around health research. Despite its shortcomings, informed consent is still fundamental to health research, but we should recognise its strengths and limitations. More consideration is needed on how to develop better ways to enable the basic requirements of informed consent to be enacted through digital mechanisms that are responsive to the characteristics of data-intensive research. Further research needs to be directed to how the governance of health research should adapt to this new complexity.

[49] J. Allen, 'Group Consent and the Nature of Group Belonging: Genomics, Race and Indigenous Rights', (2009) *Journal of Law, Information and Science*, 20(2), 28–59.