DUNEDIN MULTIDISCIPLINARY HEALTH AND DEVELOPMENT STUDY

(The Dunedin Study)

POLICY STATEMENT & CODE OF PRACTICE FOR INVESTIGATORS

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INTRODUCTION

THE DUNEDIN MULTIDISCIPLINARY HEALTH AND DEVELOPMENT STUDY

The Dunedin Multidisciplinary Health and Development Study (the 'Dunedin Study') is an ongoing longitudinal investigation of the health and behaviour of a complete birth cohort that was drawn from the greater Dunedin Metropolitan area (population 120,000), located in the South Island of New Zealand. It was established at age 3 when the participants born between 1 April 1972 and 31 March 1973 and still resident in Dunedin were followed up for the longitudinal study.

The Leadership of the Study is committed to the Te Tiriti o Waitangi (The Treaty of Waitangi signed between Māori, the indigenous people of New Zealand, and the Crown) as its foundation. The Dunedin Study has a 'Responsiveness to Māori Policy", developed by Māori Study researchers. For the detailed statement, please see Appendix A.

MISSION STATEMENT

The Dunedin Multidisciplinary Health and Development Study was established in interests of:

- **advancing knowledge about physical and mental health, and development through multidisciplinary and longitudinal study; and**
- **advancing the health status and wellbeing of New Zealanders and others.**

The Study mission will be accomplished by scholars from appropriate disciplines working together as a team. These scholars will have freedom to carry out their scientific projects as they see fit but taking careful account of the constructive advice of their colleagues involved in the Study.

The welfare of the overall Study is the responsibility of the Director, who has the ultimate responsibility to all other investigators and stakeholders for ensuring the success of the study for the indefinite future.

Three characteristics of the Dunedin Study make it unique. First, it is a longitudinal study of a general population sample. Second is the multidisciplinary nature of the Study which represents not only a broad spectrum of disciplines and topics, but also depth in measurement (conducted at the Research Unit e.g. cardiovascular-respiratory health, dental health etc.). Third is the a very high retention rate. Study members have been assessed on numerous occasions over a period of five decades, with minimal attrition. For an overview of the Study see Poulton, Moffitt, and Silva, (2015) doi: 10.1007/s00127-015-1048-8

The following policy statement and code of practice was written to protect the special characteristics of the Study in order to help secure the Study's future and achieve the Study mission.

LEADERSHIP STRUCTURE

THE GOVERNANCE BOARD

Members of the Dunedin Study Governance Board consist of the following :

- Independent Chair: Laura Black
- Pro-Vice Chancellor, Division of Sciences (Professor Richard Barker)
- Deputy Vice Chancellor, Research and Enterprise (Professor Richard Blaikie)
- Pro-Vice Chancellor, Division of Health Sciences or representative)
- Senior Professor, Department of Psychology (Professor Cliff Abrahams)
- A member of the Development and Alumni Relations Office
- Honorary Associate Professor Andrew Sporle

THE DIRECTOR (Professor Reremoana (Moana) Theodore)

The Director is leader of the scientists involved in the Study and is responsible for:

- Leading the directing the strategic and operational performance of the Study;
- Ensuring that the Study aligns with the University of Otago's Vision and Strategic Direction;
- Ensuring the smooth and effective running of the Study, including meeting its financial and regulatory obligations and delivering on its agreed programme of work
- Ensuring the continuation of good relations with, and the well-being of Study members;
- Establishing, developing, and nurturing strong networks of collaboration within the Study, nationally and internationally;
- Representing the Study to key stakeholders;
- Representing the Study to the public and through the media and promoting the activities of the Study;
- Ensuring the efficiency and scholarly productivity of the Study;
- Leading the preparation of many publications and providing advice and critical comment on all others;
- Maintaining the good reputation of the Study;
- Regulating, controlling and enabling access to data according to the policies of the Unit an ensuring security and safety of data;
- Reviewing/approving all manuscripts for submission for publication;
- The employment and supervision of all those working in the Unit and all personnel working with Study Members, and for their proper conduct;
- All contact and correspondence with Study members, although this may be delegated;
-
- The conduct of the overall study, including the maintenance of scientific and ethical standards, and the co-ordination of studies and personnel.

THE ASSOCIATE DIRECTOR (Professor Terrie Moffitt)

Professor Moffitt is recognised for her long and highly influential association with the Dunedin

Study by being given the honorary appointment of Associate Director. Professor Moffitt was appointed to this role by the Study founder Dr Phil Silva, and re-endorsed when Richie Poulton became Director in 2000. Her role as Associate Director is to assist the Director with the scientific direction of the Study, formulation of policy and provide assistance and advice to the Director as needed.

UNIT ADMINISTRATIVE AND ASSESSMENT STAFF

All staff working at the Unit, and especially those who have contact with Study members or their families must maintain the highest level of professionalism. All research assessment staff must also have the appropriate tertiary qualification. All appointments to such positions must be approved by the Director who is ultimately responsible for their work. Line responsibilities will vary but all those working in the Unit or with Study members will be ultimately responsible to the Director who, in turn, is responsible for the work of the Unit, the conduct of the Study and the wellbeing of Study members.

Research Fellows or Assistant Research Fellows reporting to Study Investigators but not employed at the Unit and not having contact with Study members, are not the responsibility of the Unit. However, the Study Investigators employing them are responsible for ensuring that the Unit policies are understood and followed. They should be familiar with this document and should, for example, have a thorough understanding of the need for respecting the principles of confidentiality and the Study requirements concerning publications.

SCIENTIFIC INVESTIGATORS

LEAD INVESTIGATORS

Lead Investigators share the responsibility across a number of broad research themes that include: mental health and cognition, cardiovascular health, psychosocial functioning, respiratory health, sexual behaviour and reproductive health, and oral health. Māori health (the indigenous people of New Zealand) is led by the Director and supported by Māori lead investigators.

Lead Investigators will be responsible for scientific and methodological aspects of the conduct of their own studies, and of ensuring their team members are cognisant of the policies and procedures of the Study. Lead Investigators are researchers who are expected to obtain funding to collect data for their area of research. Lead Investigators will be invited to join the Study by the Director.

CO-INVESTIGATORS (CI's)

One or more investigators may be nominated by Lead Investigators as co-investigators of particular studies. This is subject to approval by the Director.

ASSOCIATED INVESTIGATORS (AI's)

Researchers are able to apply to become an Associated Investigator of the Dunedin Study to gain access to data and conduct their research. This can be done via a Lead Investigator with approval from the Director. An application should include a current curriculum vitae and a concept paper describing the aims, methods, significance and publication(s) planned, and the data that is required. The application will be considered against the following criteria:

- Public health value of the project.
- Availability of data in the Study to ensure a meaningful test of the hypotheses.
- The project is not already contracted for by another investigator/funding agency.
- A Lead Investigator is available for sponsorship/supervision.

ETHICS

All components of the Dunedin Study must receive ethical approval before the commencement of an assessment phase. This is co-ordinated by the Director. Lead Investigators will be held to be scientifically and ethically responsible for their studies. Lead Investigators may also need to seek ethical approval from their own institutions.

CONFIDENTIALITY

We have promised Study members, their parents, their children and their friends that all information we collect is for research purposes only. It is strictly confidential and never released to anyone outside the Study unless Study members request it. All staff need to be aware that volitional breach of confidentiality would be grounds for instant dismissal. To date, there have been no known breaches of confidentiality.

Under no circumstances will names of Study members be given to the media, even with their consent. We recommend that the media use actors and not Study members for any portrayal of the Study.

WELL-BEING OF STUDY MEMBERS

The well-being of Study members (and their families) is paramount. At each assessment phase, staff training will include procedures for ensuring the well-being of Study members.

CONTACT WITH STUDY MEMBERS

All written contact with Study members must be over the signature of the Director, unless delegated by the Director. No Lead Investigator, other researcher or staff member shall contact any Study member for any reason without the Director's knowledge and approval. This has always been the case and avoids Study members becoming confused about conflicting requests for information.

DATA

DOCUMENTATION AND SECURITY OF DATA

It is essential for the maximum use and protection of the data that copies of **all** data sets are held by the Dunedin Multidisciplinary Health and Development Research Unit and at other nominated safe sites as well (e.g., Duke University under the control of the Associate Director Professor Terrie Moffitt). These data sets must be fully documented in the Unit's data directories in such a way that they can be understood by others who may obtain permission to use them.

Responsibility for documenting the data and ensuring its security lies with each Lead Investigator, or researcher conducting the project. As part of the approval to conduct a specific project, the proposing author signs a Data Security Agreement (see Appendix B2)

Over the years, many new variables ("derived variables") have been created for specific studies. These variables, together with full documentation should be lodged at the Unit upon publication.

Raw data forms should not be removed from the current storage sites under any circumstances.

RESPONSIBILITIES FOR USE OF DATA

The Dunedin Multidisciplinary Health and Development Research Unit is responsible for all data collected as part of the Dunedin Multidisciplinary Health and Development Study, as well as the sub-studies, Parenting Study and the Next Generation Study, regardless of the source of funding.

All data are available to all Dunedin Study researchers with reference to key policies like the Māori Responsiveness Policy. It is emphasised that where a substantial portion of discipline-specific data set is to be used, the investigator should consult the researcher responsible for funding the collection of those data at an early stage as a matter of courtesy and to ensure that the variables to be used are being correctly interpreted. "Substantial", in this context, may mean multiple variables or variables which are central to the area of research. Secondly, the investigator who proposes using the data should consult with others who have demonstrated an ongoing interest in the proposed research topic. In such cases, these investigators should be offered an opportunity to participate in the proposed research. If co-authorship is declined, these investigators should be given the opportunity to read and comment on the paper prior to submission to the Director.

Investigators may collaborate with other investigators beyond the Unit in the analysis of data and reporting of results. They should, however, inform the Director at a preliminary stage about the proposed area of study, prior to submitting specific proposals via the concept paper protocol.

ACCESS TO DATA

The Dunedin Study data (including observational, self- or other-reported, all biological or physiological assays, and linked national/official/agency data) are not in the public domain. The agreement required by the New Zealand Ethics Committee stipulates that Study members' data will only be available to the members of the Dunedin Study research team. Those not currently involved in the Study can seek access to data via the Associated Investigator mechanism (described above). The study actively seeks opportunities to collaborate with other reputable researchers, in pursuit of important scientific and/or public policy questions.

For a discussion document on data sharing in the Dunedin Study, please see Appendix C.

PUBLICATIONS

THE UNIT'S GENERAL POLICY RELATING TO PUBLICATIONS

All research carried out as part of the work of the Unit is expected to result in publications in scholarly peer reviewed journals, monographs or books, and these reports are the main basis on which the investigator's work is judged. All researchers are expected to start producing papers as soon as data collection is completed.

It is the responsibility of all investigators to provide the Director - on a regular basis - with details of the process of publications i.e., in press, under consideration for publication, nearly completed or planned (via concept papers) for the near future in order for the Unit's publications database to be maintained.

It is expected that Lead Investigators will have shown evidence of progress in analysing/reporting data and publishing from a particular Phase within a period of two years from the date of final collection of the data. If, in the opinion of the Director, such progress has not been made, and after consultation with the investigator concerned has taken place, consideration would be given to approaching other investigators to assume responsibility for reporting the results of that research.

CONCEPT PAPERS

The concept paper is the process the Study has used to log (for the public record) and track each project within the Study. It allows for comments and exchange of ideas at the proposal level and ensures that the relevant members of the wider Dunedin Study team have an opportunity to contribute. Please see Appendix B for a description of the process and the template.

ACKNOWLEDGEMENTS AND APPROVALS

When submitting an article for publication or presenting a paper, it is important that the contribution of agencies or individuals that supported the research be properly acknowledged. Thus, in addition to acknowledging the author's particular funding bodies, all publications should acknowledge the Health Research Council of New Zealand and the Ministry of Business, Innovation and Employment, and where appropriate other funding bodies which have supported the data collection over many years, that is, agencies from the United States and the United Kingdom. The Director or Lead Investigator responsible for the data collection should be consulted to ensure that all funding bodies are appropriately acknowledged (e.g. with correct grant numbers etc.).

The contribution of the Study members, their families and friends should always be mentioned in the acknowledgements section. Please see Appendix B for the current list of acknowledgments

FINAL APPROVAL OF PUBLICATIONS

It has always been the Unit's policy that any publication from the Research Unit must be approved by the Director before it is sent off for consideration for publication. The Director will thus have an opportunity to comment on such matters as the description of the sample and methodology, appropriate referencing of the Unit's publications, appropriate acknowledgement of those who have contributed, as well as on the science. This will also ensure consistency with earlier publications from the Study. The Director may, in some instances, refer a paper to an acknowledged expert in the field to get an independent comment. No paper using data from the Unit may be offered for publication without the approval of the Director.

Papers to be presented orally at conferences or meetings need not be approved in the above manner unless they are to be published.

DISPUTES

The Director has a responsibility to safeguard the rights of those who raised the funds to collect the data and to ensure that the comprehensive data set is used to the full to advance knowledge about health and development. Any problems, including those related to determining "guardianship" of data, access or use of data and publications, should be referred to the Director for clarification. Unresolved problems may be referred by the Director to the Governance Board for their consideration.

The above procedures have been developed to resolve disputes of any kind within the Unit. They should be used before raising contentious issues with other bodies.

SPEAKING FOR THE UNIT AND THE INDIVIDUAL STUDIES

Only the Director or their nominee (most typically the Associate Director) are allowed to speak on behalf of the Dunedin Multidisciplinary Health and Development Research Unit or overall Study (e.g. to the media or agencies). Researchers or those authorised by them, are free to speak about their own studies, but should inform the Director if they are reported by the media. Copies of media releases should be provided to the Director prior to release.

CONCLUDING REMARKS

This policy document and code of practice is set to out to aid with the Study's mission. Consultation, collaboration and co-operation lead to better quality work and protect the rights of all involved, Researchers should encourage and assist each other as much as possible, especially in the use of data, to increase the overall scholarly productivity. The study enjoys the privilege and responsibility of the gift of data ('taonga' in Te Reo Maori) from the Study members, their families and friends. Our role as researchers is to honour our commitment to them by maximizing the use of the data for the betterment of future generations.

For correspondence regarding this document, please contact:

Dr. Sandhya Ramrakha
Research Manager
Dunedin Multidisciplinary Health and Development Research Unit
sandhya.ramrakha@otago.ac.nz

February 2024

Appendix A

THE UNIT'S RESPONSIVENESS TO MĀORI POLICY

The Dunedin Study '**Responsiveness to Māori Policy**' has a commitment to the Te Tiriti o Waitangi as its foundation. The policy, which has been led by Māori researchers, in partnership with Dunedin Study leadership, has been developed and built on over time. The policy includes: acknowledgement of the need to maximise the Study's contribution to Māori health; acknowledgement of Māori tino rangatiratanga over Māori analyses within the Study; active consultation with key Māori stakeholders; and a commitment to build and support a Māori workforce capacity within the Study.

Dunedin Study research team: All members of the Dunedin Study team: (i) recognise the Articles of the Treaty of Waitangi, (ii) develop strategies for responsiveness to Māori aligned with the Articles; and (iii) operationalise these strategies. Specifically, Article 2 articulates the retention of Māori control (tino rangatiratanga) over Māori resources, including people and Māori analyses and data. Article 3 provides a right to equitable health outcomes. According to the HRC, "For health research, Article Two results in recognition that iwi and hapū have an authority over their peoples' involvement in research. Article Three generates an expectation for both an equivalent state of health between Māori and Pakeha, and an equitable share of the benefits of any Crown expenditure".

Protection of Maori participants: The Dunedin Study is a study of three generations of New Zealanders and has clear obligations to Māori study members, their whānau, including their parents, their children (and their partners). It is thus critical to have policies that protect Māori Study participants and their whanau. Our aim is to protect and uphold their integrity, while at the same time maximising the contribution the Dunedin Study can make to Māori health and well-being.

Workforce development: Māori workforce development is a key aspect of responsiveness to Māori. We do this through supporting and enhancing collaboration and also research development within the study. The Dunedin Study Director is a senior Māori health researcher and is supported by other senior Māori Lead Investigators.

Researcher responsibility: The Dunedin Study Responsiveness to Māori Policy requires all researchers to be aware of, and follow through on, the following: (a) The Dunedin Study and its researchers have a commitment to meeting responsibilities and obligations to Māori under the Treaty of Waitangi; (b) The need to consult with Māori when and wherever appropriate. It is acknowledged that Ngāi Tahu has a preferred process for consultation about research and the Dunedin Study has a commitment to supporting this process; (c) Māori workforce development and Maori researcher support/supervision. Lead Investigators will work with Director in the development of Māori workforce; (d) Māori data.

Data analyses and report writing: The Director working with Lead Investigators will conduct studies relevant to Māori health using data collected as part of the Dunedin Study. All ethnicity-related analyses need to be done in partnership with the Director and Māori Lead Investigators. A key concern for the Dunedin Study is superficial analyses of data that simply identify differences or deficits between ethnic groups or other communities where inequities exist (e.g. persons with disabilities, Pasifika peoples, members of migrant and SOGIESC (Sexual Orientation, Gender Identify and Expression and Sexual Characteristiocs) communities. The cumulative effect of these types of studies is stigmatising and not of benefit. Any research that identifies differences must (a) incorporate information on the broader context (e.g. historical or political factors); (b) where possible undertake additional analyses to examine the source of the difference/s, and (c) include policy recommendations for its resolution. Dissemination beyond normal academic channels is expected. This might include attendance at dissemination hui and development of resources based on research.

New policy mechanisms: As new issues relevant to Māori health arise, these will be addressed and incorporated into the Dunedin Study Responsiveness to Māori Policy document. Currently, there is further policy development occurring regarding (i) addressing tikanga aspects of the collection, storage, analysis and disposal of blood and tissue samples (ii) particular issues associated with genetic aspects of the research and (iii) further avenues and means of dissemination to Māori.

Appendix B

Appendix Section B(1): THE DUNEDIN STUDY CONCEPT PAPER PROCESS

- Develop the concept proposal with your Lead Investigator sponsor.

- Submit the concept paper to Study Director, director.dunedinstudy@otago.ac.nz. The Director may nominate others in the Study team for involvement in the project.
  Please cc Research Manager, Sandhya Ramrakha sandhya.ramrakha@otago.ac.nz

- You are advised to consult those in the Dunedin Study team with expertise in specific areas of the project when formulating the CP. If unsure, please consult the Director.

- Description of Dunedin Study – please use existing boiler plates for the methods section for consistency across publications. No need to re-invent the wheel.

- Circulate the manuscript for review to all co-authors, including the Director for final approval. Allow 3 weeks.

- Note: All the analyses need to be checked by an independent biostatistician before submitting for publication.

- Send the submitted version to Dr Sandhya Ramrakha sandhya.ramrakha@otago.ac.nz and Cody McRae (Unit Administrator) cody.mcrae@otago.ac.nz for the Unit's records. Please keep them informed of progress, i.e. re-submission to a different journal, acceptance, when available online and in print.

- If there is a press release accompanying the publication, please notify the Director and Research Manager and send a copy of the press release to them.

- Final step: Please lodge with the Unit, through the Research Manager, all new variables created for this project by sending a system file and documentation. Include the variable labels and value labels. Documentation includes how you made the variable and its frequency distributions, including the derivation code used to create each variable from the base-data variables themselves (i.e. before any re-codes etc.) This makes it easier to see exactly what was done.

Appendix Section B(2): CONCEPT PAPER TEMPLATE

DUNEDIN MULTIDISCIPLINARY HEALTH AND DEVELOPMENT STUDY

(The Dunedin Study)

CONCEPT PAPER TEMPLATE

(June 2021)

DUNEDIN STUDY CONCEPT PAPER

Provisional Paper Title:

Proposing Author:

Author's Email:

P.I. Sponsor:
(if the proposing author is a student or colleague of an original PI)

Today's Date:

Please describe your proposal in 2-3 pages with sufficient detail for helpful review.

Objective of the study:

Data analysis methods[1]:

Variables needed at which ages:

Significance of the Study (for theory, research methods or clinical practice):

References:

[1] A key concern for the Dunedin Study is superficial analyses of data that simply identify differences or deficits between ethnic groups or other communities where inequities exist (e.g. persons with disabilities, Pasifika peoples, members of migrant and SOGIESC (Sexual Orientation, Gender Identify and Expression and Sexual Characteristiocs) communities). The cumulative effect of these types of studies is stigmatising and not of benefit. Any research that identifies differences must (a) incorporate information on the broader context (e.g. historical or political factors); (b) where possible undertake additional analyses to examine the source of the difference/s, and (c) include policy recommendations for its resolution.

Data Security Agreement

Provisional Paper Title	
Proposing Author	
Today's Date	

Please keep one copy for your records and return one to the PI Sponsor

Please initial your agreement: (customize as necessary)

	I am current on Human Subjects Training [CITI www.citigrogram.org] or equivalent.
	My project is covered by the Dunedin Study's ethics approval OR I have /will obtain ethical approval from my home institution (please specify).
	I will treat all data as "restricted" and store in a secure fashion. My computer or laptop is: • encrypted (recommended programs are FileVault2 for Macs, and Bitlocker for Windows machines) • password-protected • configured to lock-out after 15 minutes of inactivity AND • has an antivirus client installed as well as being patched regularly.
	I will not "sync" the data to a mobile device.
	In the event that my laptop with data on it is lost, stolen or hacked, I will immediately contact my PI Sponsor or Study Director, Richie Poulton (richie.poulton@otago.ac.nz).
	I will not share the data with anyone, including my students or other collaborators not specifically listed on this concept paper.
	I will not post data online or submit the data file to a journal for them to post. *Some journals are now requesting the data file as part of the manuscript submission process. The Dunedin Study Members have not given informed consent for unrestricted open access, so we have a managed-access process. Speak to your PI Sponsor or Richie Poulton for strategies for achieving compliance with data-sharing policies of journals.*
	I will delete all data files from my computer after the project is complete. Collaborators and trainees may not take a data file away from the office. The data remains the property of the Study and cannot be used for further analyses without an approved concept paper for new analyses.

Signature: _____

CONCEPT PAPER RESPONSE FORM

A To be completed by the proposing author:

Provisional Paper Title	
Proposing Author	
Other Contributors	
Potential Journals	
Today's Date	
Intended Submission Date	

Please keep one copy for your records and return one to the proposing author

B. To be completed by potential co-authors:

☐ Approved ☐ Not Approved ☐ Let's discuss, I have concerns

Comments: _____

_____

_____

_____

Please check your contribution(s) for authorship:

	Conceptualizing and designing the longitudinal study
	Conceptualizing data collection protocols and creating variables
	Data collection
	Conceptualizing and designing this specific paper project
	Statistical analyses and interpretation (or reproducibility check)
	Writing
	Reviewing manuscript drafts
	Final approval before submission for publication
	Agreement to be accountable for the work
	Acknowledgment only, I will not be a co-author

Signature: _____

Appendix Section B(3): ACKNOWLEDGEMENTS (May 2021)

We thank the Dunedin Study members, their families and friends for their long-term involvement. [Also acknowledge Dunedin Study members' [teachers], [partners], [children] and [peer informants], where these data are used.]

Thank Dunedin Unit Director, Professor Reremoana (Moana) Theodore [if not a co-author), Unit research staff, [names of principal investigators who shared data with you, if they are not co-authors], previous Study Director, Emeritus Distinguished Professor, the late Richie Poulton, for his leadership during the Study's research transition from young adulthood to aging (2000-2023)and Study founder, Dr Phil A. Silva.

Also acknowledge those who provided research assistance and helpful comments on earlier drafts.

The Dunedin Multidisciplinary Health and Development Research Unit is supported by the New Zealand Health Research Council, and has also received funding from the New Zealand Ministry of Business, Innovation and Employment. Please also acknowledge current funding from

- The New Zealand Health Research Council Programme Grant (16-604)
- The US-National Institute of Aging Grant R01AG032282-11 (for Phase 52)
- The US-National Institute of Aging Grant P30AG034424 (for exposome work)
- The UK Medical Research Council grant MR/X021149/1 (for phase 52 funding)
- US NIA AG049789-06: Quantifying Individual Differences in Midlife Structural Brain Integrity Associated with Later AD/ADRD Risk "

Appendix C: DATA SHARING IN THE DUNEDIN STUDY

We are enthusiastic about the open-science movement to enhance reproducibility (http://www.sciencemag.org/content/348/6242/1422.full?ijkey=ha1o5D9wvW4ZQ&keytype=ref&siteid=sci). The Dunedin Study has had a data-sharing policy in place for over 20 years, and we are registering all data-analysis plans on our website: https://dunedinstudy.otago.ac.nz/for-investigators/concept-papers-2020

We seek a careful balance between the benefits of data-sharing in research and any potential risks to study participants. Seeking this balance is aided by consultation of research and policy on data sharing. For example, in August 2014, NIH issued its Genomic Data Sharing (GDS) Policy. This policy is intended for investigators who intend to generate large-scale genomic and phenotypic data from federally funded new collections, and the Dunedin Study is not among that group. Nevertheless, we think the basic principles of the GDS Policy apply well to data sharing in general across many types of data. To explain our own policy, we draw on published materials from the GDS Policy (http://osp.od.nih.gov/under-the-poliscope/2015/08/genomic-data-sharing-two-part-series). This document is intended to give interested parties a full explanation of our data sharing policy, and the longstanding rationales behind it. The document ends by describing the requirements for accessing Dunedin Study data.

The 2014 NIH GDS Policy establishes that data-sharing can only occur with the advance consent of research participants, even if the datasets generated have been de-identified. NIH now takes this approach to informed consent because formal research into participants' preferences document that participants expect to be asked for permission before scientists use and share their de-identified data for research (for a special issue on this research see The End of Privacy, *Science* 22 Feb 2015, www.sciencemag.org). Moreover, as has been well-documented, the risk of re-identification of data, particularly genomic data, is no longer a theoretical possibility and re-identified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. As such, it is no longer tenable for scientists to hold that anonymization is still achievable or to allow unrestricted sharing of "de-identified" datasets without consent on the premise that de-identified use is without risk to the donor. The GDS Policy urges that the research enterprise must begin to respect the wishes of participants in relation to data access.

We have not sought informed consent for unrestricted data sharing because data from the Dunedin study have historically been deemed as being in a **high-risk** category that precludes making the data set available for unrestricted unsupervised open-access data sharing. Consent documents for the study used since its inception have informed each study member that "Your data are held in strict confidence," and "Only members of the Research Unit team will have access to your data." These consent documents were last signed by Study members at the age-45 assessment, which ended in 2019. This means that the Dunedin Study participants have not at this point given their informed consent for unrestricted data sharing, and therefore data deriving from them cannot be made available for unrestricted use.

There are 5 main reasons for the Dunedin Study's approach to informed consent and data sharing, each derives directly from the special circumstances of an ongoing 5-decade longitudinal multi-generational study of a birth cohort of human participants and their families. We note each below.

1. **Risk of mental pain and suffering.** The research team and IRBs recognize the risk to study members of mental pain and suffering from worry about the security of their lifetime of data. Due to the depth, multidisciplinary breadth and duration of the Dunedin Study, this dataset differs markedly from data sets created when research participants take part in a one-time limited data–collection session. The Dunedin data set contains sensitive information regarding topics concerning participants' IQ, income, health behaviors, credit ratings, conviction records, social welfare records, and medical records. Unusual in research, the data set includes information divulged by study participants in confidential interviews about, for example, their lifetime history of mental disorders, sexual preference, suicidality, physical and sexual abuse victimisation, substance use, high-risk sexual behavior, domestic violence, life events such as abortions and divorce, parenting of children, and crimes committed. Also unusual, the data set contains information about the medical and psychiatric histories of four generations of the study members' families, from their grandparents to their offspring. Since the 1990's the data set contains genetic and genomic data and biomarker data, which have special ethical status because they allow re-identification, and because researchers are in the position to know information about study members' genes and health that they themselves do not know. As reported in all publications from the study, the cohort members are born during an identifiable year in an identifiable city and they are from a small-population country. An ill-intentioned user could very easily misuse the data of the longitudinal study to illicitly identify individual study members and their families, and to expose confidential and potentially destructive details of their lives. The likelihood of any scientist doing this is immaterial. *What is material is the study members' perceptions of the potential for data-security risk, and their concerns about it.*

2. **At-risk participants.** Substantial proportions of the cohort belong to at-risk groups. It is standard ethical policy that such groups require a simple-to-understand, unconditional guarantee that all of their data are held in strict confidence by the research team. These groups include incarcerated prisoners, patients with chronic mental illnesses (such as schizophrenia or autism), and individuals whose tested cognitive abilities are in the diagnosable range of mental retardation or mild cognitive impairment. For these groups, trust is achieved by putting a face on who will use their data, and this is inconsistent with seeking consent for unrestricted data-sharing.

3. **Multiple suppliers of data.** Because this study has been underway for almost five decades, much of the data were collected from individuals who gave informed consent under the condition that data would be kept strictly confidential and used only by the Dunedin Study research team, including mothers, fathers, teachers, peer informants, partners, schools, doctors, government agencies, and private companies who provided administrative data. These Dunedin Study various data sources are not now accessible to us for re-consent and therefore data derived from them cannot be shared for unrestricted use.

4. **Risk of cohort attrition caused by concerns about data security.** The Dunedin study will be actively ongoing for years into the future. The scientific value of the longitudinal design relies on future follow-ups of the cohort, and high participation rates at those future follow-ups. As such, the benefits of data-sharing for a single paper project in the short run must always be weighed against the greater benefit of preserving the cohort intact for the multi-decade longitudinal study as a whole in the longer run. Our surveys of our cohort members indicate that their continued participation is contingent on the consent forms' stating that "Your data are held in strict confidence" and "Only members of the Research Unit research team will have access to your data."

5. **Growing public concern about data security stimulated by media coverage.** The Dunedin Study families were first enrolled in the study many years ago, in a kinder, gentler era. Their first two decades of participation were marked by enormous trust in the research team, which was based on personal contact between researchers and families, and on our proven track record for preserving participants' confidentiality. In the early days, the Dunedin Study was not internationally visible, data were not kept in electronic format, genomic and biomarker data were not collected, requests for data-sharing could be handled by a welcoming stance toward collaboration, and the movement for unrestricted open-access data-sharing had yet to emerge on the scientific scene. However, times have changed. Today, efforts to recruit research participants routinely fail, so much so that the National Academy of Sciences convened a panel to address the problem, which is in part due to public lack of confidence in data security (Massey DS, Tourangeau R. New Challenges to Social Measurement. Annals of the American Academy of Political and Social Science. 2013;645:6-22). Some Dunedin members have contacted us in reaction to media coverage reporting that research participants and their families can easily be identified using only their DNA, age, and city (for example: http://www.nytimes.com/2013/06/18/science/poking-holes-in-the-privacy -of- DNA).
   Such media coverage is changing the way that cohort members think about their lifetime repository of data in the Dunedin Study. Media coverage of "The Surveillance Society," portrayal of forensic science in television and film (such as CSI), and news stories of criminal hackers accessing supposedly secure government and industry data bases, appear daily. Thus the IRBs recognize that an ironclad guarantee of confidentiality is essential to make study members feel safe, prevent mental pain and suffering caused by worries about data security, and to prevent cohort attrition.

The 2015 version of the Helsinki Declaration addresses the potential for conflict between the aims of open-access data and the aims of human-subjects protection: Principle 8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects (http://jama.jamanetwork.com/article.aspx?articleid=1760318).

Our data-sharing policy provides for researchers outside the Study to access data by applying for Associated Investigator as described earlier in this document (page 8 ACCESS TO DATA). Researchers are invited to submit a concept paper describing the data analysis project they wish to carry out. The applicant investigator is then nominated for a non-salaried appointment as an "Associated Investigator," under the sponsorship of a study Lead Investigator, for a limited term corresponding to the duration of the project. We provide all such investigators with clean, well-documented data files and electronic data- set dictionaries. To ensure effective data sharing, the Lead Investigator-sponsor discusses detailed data-analysis plans with each investigator in advance and stays actively involved throughout each project. Our involvement is required because the IRB has long required that consent forms must include "The name and contact information of an individual who is affiliated with the institution and familiar with the research and will be available to address participant questions." (NIH GDS Policy requires this as of January 2015). We provide participants with the names and contact details of Lead Investigators at the time of consent.

Access requirements in a nutshell. Proposed data-analysis projects from qualified scientists must have a concept paper describing the purpose of data access, IRB approval at the applicants' university, and provision for secure data access. We offer secure access on the Duke and Otago campuses. These access requirements parallel those used by dbGap and the Health and Retirement Study.

Voluntary data-sharing. This data-sharing policy has been in place and operating effectively for over 20 years. It is useful to keep in mind that the Dunedin Study's data sharing has always been voluntary, not compelled. Unlike dbGaP and the HRS, the Dunedin Study has never been funded as a data provider. In addition, much of the data, including the genomic data, were not funded by US taxpayers. Like the large Scandinavian register data bases who require travel to Scandinavia to access their data, the Dunedin Study contains data on non-US citizens only but the Dunedin Study makes data available in the USA, without travel to New Zealand. Our data-sharing policy was last approved in 2015 by NIA as part of review of Dunedin Study competing-renewal funding.

Data sharing in the New Zealand context: The following is a link to a paper recently published which explores data sharing issues in the Aotearoa New Zealand context. doi: 10.1080/1177083X.2021.1922465