Waiver of consent projects

Consent to participate in research is an ethical gold standard that upholds respect for the research participants involved. However in some cases it is not possible to seek explicit consent, and the circumstances of an individual project may justify employing an opt-out approach or a waiver of the requirement for consent.

The National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research guides Human Research Ethics Committees (HREC) and researchers in these cases where it is not practicable to seek consent. In order to approve such a study, the HREC must be satisfied that all necessary criteria are met, for example the research must be low risk, and the benefits from the research must justify any risks of harm associated with not seeking consent.

If a HREC grants a waiver of consent for research conducted prospectively or retrospectively, research participants will characteristically not know that they, or perhaps their tissue or data, were involved in the research. As such, the RCH HREC makes publicly available the list of projects where a waiver of consent has been approved. Please see here the list of projects approved in 2021.

Study Details	**Waiver of consent**
Generation Victoria (GenV) PI: Prof Melissa Wake (HREC 2019.011) Generation Victoria, or GenV for short, is a state-wide research project run by the Murdoch Children's Research Institute (MCRI). It will give a complete picture of the health and wellbeing of an entire generation. Over two years, all babies born in Victoria, and their parents, are invited to take part. We want to include all babies and parents, no matter who they are or where they live. Every family matters - including yours. GenV combines information you provide with data already collected by other services. This means it takes very little of your time. Future research can then find answers to complex health and wellbeing questions faster than we can today. We hope GenV will help to prevent, predict and treat the issues facing children and parents today. We want to see less problems like preterm birth, allergies, mental illness for everyone.	The RCH HREC approved a waiver of consent to transfer limited personal information from the Victorian Infant Hearing Screening Program (VHISP) to the MCRI. This enables the research team to identify participants who are eligible for the study. They will approach them in maternity hospitals, with permission by the treating clinical team. Written consent is sought to be included in the project. If families cannot be approached in hospital, they will be provided with information about Gen V to take home. Unless the parents says otherwise, the research team will try to contact them about being involved in the research project. Written consent is sought to be included in the project.
Retrospective review of paediatric patients treated with radiation PI: Jordan Hansford (HREC 73620) The aim of the study is to provide retrospective clinical data from a cohort of paediatric patients from Australia to compare with a partner institute in Canada.	The RCH HREC approved a waiver of consent for data linkage of patient records from The Royal Children's Hospital and Peter MacCallum Cancer Centre using personal identifiers. Once the data is linked, it will be analysed with personal identifiers removed.
Generation Victoria biospecimen pilot study: assessing the utility of samples for inclusion in a state-wide collection PI: Prof Richard Saffery (HREC 69151)	The RCH HREC approved a waiver of consent for the use of excess and anonymous biosamples, such as GBS swabs, that would otherwise be discarded.

This study aims to determine how to optimally collect, store, and process samples to ensure research utility for the Generation Victoria Biobank	Samples are non-identifiable. They cannot be re-identified and will be discarded after the tests are completed.
Study of neck injuries in children (SONIC): A prospective, observational study to develop a new or validate existing international clinical decision rules for children presenting to the emergency department with suspected cervical spinal injuries. PI: Franz Babl (HREC 69439) This project is part of a national study on children who are seen in the emergency department with a possible neck injury. The study is being conducted at more than 10 major hospitals in Australia and New Zealand and is funded by an Australian Government grant. As part of this study, we want to get a better understanding of which children attend hospital with possible neck injuries. We also want to improve the care of these children. While some children with possible neck injuries can be discharged home without special tests or treatment, others may require X-rays or other scans. This study will help us determine which children who have a possible neck injury require further imaging tests such as x-rays and scans.	The RCH HREC approved a waiver of consent for collection and use of routine clinical data (de-identified) by MCRI from the participating hospitals.
Burns registry of Australia and New Zealand PI: Warwick Teague (HREC 29011) The Burns Registry of Australia and New Zealand (BRANZ) captures epidemiological, quality of care, and in-hospital outcome data for adult and paediatric burns patients across Australian and New Zealand burns units. The Australian and New Zealand Burns Association (ANZBA) established BRANZ in 2004 in recognition of the need to capture accurate data relating to burns admissions across Australia and New Zealand.	The RCH HREC approved an opt-out approach to consent for personal information of eligible patients to be sent researchers at Monash University. This enables the researchers to contact participants to seek consent for their outcome measures included on the Burns Registry. All patients are provided with written material advising them that their contact details will be shared. If patients do not wish to be contacted, or have their contact information shared, they have the option to actively decline.
WHO Severe Acute Respiratory Illness (SARI) & Respiratory Syncytial Virus (RSV) Surveillance in Australia PI: Nigel Crawford (HREC 37185) The purpose of this study is to determine the proportion of RSV positive severe acute respiratory infections (SARI) cases are hospitalised at Australian paediatric hospitals. This information will contribute to the second phase of the World Health Organisation (WHO) led global data collection.	The RCH HREC approved a waiver of consent for the collection and reporting of de-identified health information from participating hospitals to MCRI, and the sending of clinical samples to the WHO Collaborating Centre in Melbourne for genomic analysis.
Sustaining improvements in the management of infants with bronchiolitis PI: Emma Tavendar (HREC 72517) This study is evaluating the sustainability of improvements in bronchiolitis management. The researchers will undertake a retrospective audit of medical records and qualitative interviews with staff at participating sites.	The RCH HREC approved a waiver of consent for the extraction of retrospective de-identified data on bronchiolitis care from medical records of children treated in 2018-19 at participating hospitals in Australia and transfer to MCRI.
Real world experience of direct-acting antiviral treatment in Australian children with chronic hepatitis C PI: Dr Jessica Eldredge (HREC 75391)	The RCH HREC approved a waiver of consent for the collection and use of de-identified health information from each participating hospital sent to RCH for analysis.

This multi-site study seeks to determine the number of Australian children treated with direct-acting antiviral agents and the rates of cure (sustained viral remission 12 weeks after treatment), via a review of medical records from five Australian paediatric tertiary hospitals.	
Pharmacological emergency management of agitation in Children and Young people; a randomised control trial of IntraMuscular medication (PEAChY-M) PI Franz Babl (HREC 69948) The aim of the PEAChY-M study is to investigate the most effective medication to give to people aged less than 18 years with acute severe behavioural disturbance (ASBD)ss who present to the ED. Currently in Australia a range of different medications are used in the management of ASBD. There are also several different ways of giving these medications. When a young person is extremely distressed, they are unlikely to be able to take a tablet. In this case, we give them medication via an injection into the leg muscle – this is called an intramuscular (IM) injection. There have been no studies looking at which IM medication works best. In this study, we will compare two medications that are commonly used in EDs across Australia for ASBD management: Olanzapine and Droperidol. We want to find out which medication works best for young people who present to the ED with ASBD who need an IM medication. Our research project will be the first to compare these two medications in young people.	The RCH HREC approved a waiver of consent for the randomisation of young person to receiving one of two standard of care medications in an emergency situation where consent cannot be sought prior. Participants and guardians are informed of the randomisation when the situation has de-escalated and consent is sought for health information to be included in the study.
Title - Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial. PI: Dr William Garvey (HREC 67653) The study will be conducted in in 12 schools, 6 in a metropolitan Melbourne region and 6 in a rural Victoria region. Over the study period we will be assessing a model that involves educators and a paediatrician working together to better support children with emotional and behavioural difficulties in primary school.	The RCH HREC approved a waiver of consent for participating schools to pass on personal information such as name and contact details of care givers who had not responded to the letter from researchers, sent by the school, to seek consent for the study.
Title: Victorian pilot study to undertake paediatric Diagnostic Reference Level (DRL) survey in conjunction with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) PI: Ms Edel Doyle (HREC 73695) This multisite study aims to establish (up to 16 years of age) Diagnostic Reference Levels (DRLs) in Victoria for x-ray examinations. Researchers will request radiographers in local departments to record radiation dose data for a minimum of 50 paediatric patients over a 1-year period and collect age and weight (optional) of the child.	The RCH HREC approved the collection and transfer of de-identified health-information from participating radiology sites to the research team at Monash University.

Title: Evaluating the safety and effectiveness of COVID and influenza vaccines in residential aged care PI: Prof Jim Buttery (HREC 77307) This study aims to look at how effective the COVID and flu vaccines are at preventing elderly people in aged care homes from catching and getting sick with COVID-19 or seasonal flu. Furthermore, this study will look at if those who receive any of these vaccines experience any side effects or reactions.	The RCH HREC approved a waiver of consent for the transfer of de-identified data from HealthMetrics (the medical record management system for aged care facilities estimated 55,0000 cases) to the MCRI research team and their collaborators.
AIROPLANE: Air or Oxygen for Preterm Infants; an Embedded trial PI: Dr Louise Owen (HREC 78071) This study will assess the effects of starting breathing support with 30% oxygen compared with 21% oxygen. We will assess whether one or other strategy leads to babies having less need for later breathing support, less need for medication, less time in hospital, or better feeding.	The RCH HREC approved a waiver of consent for the collection, transfer, and use of limited standard-of-care data, including limited, re-identifiable data for the sole purpose of data linkage between the two AIROPLANE data collection time points. Data transfer relates to the transfer of data (including re-identifiable data) from the birth hospital to MCRI (REDCap database). Participating hospitals will be cluster randomised to deliver standard of care oxygen concentrations to newborns in the delivery room (21% or 30%).
Co-design, testing and evaluation of a new approach to community care for children and families living with adversity PI: Professor Harriet Hiscock (HREC 62866) The project aims to help services better find out about and support families who have children aged from birth to 8 years and who may be experiencing life challenges. Life challenges include feeling overwhelmed, not having enough support, feeling isolated, challenging child behaviours, money, housing, work, relationships, physical or mental health and drug and alcohol use.	The RCH HREC approved a waiver of consent for personal information (contact details) from service providers to MCRI. All potential participants are provided with a letter giving them two weeks to opt-out of their contact details being passed on. Active consent is required for participation in the study.
Determining antimicrobial pharmacokinetics and pharmacodynamics in young infants PI: Amanda Gwee (HREC 77052) This project is based at The Royal Children's Hospital Melbourne (RCH) and is looking at the pharmacokinetics (PK) and pharmacodynamic (PD) of antibiotics in neonates in the intensive care unit, aged 0 to 120 days. The overall outcome is to have a better use of using antibiotics as currently, there is not a good understanding of how it works in neonates and lots of babies are treated with antibiotics. The project will aim to fill this gap by taking an additional 2-5 blood samples and measurements of antibiotics levels.	The RCH HREC approved a waiver of consent for the collection of a small amount of extra blood at the same time as a routine clinical blood draw in circumstances where consent could not be sought prior to the routine blood draw. All parent/guardians are informed of the blood draw as soon as possible and given the opportunity to consent to the blood and health information to be used for the study.
Vaccine Safety Health Link: Near real-time automated vaccine safety signal detection using routinely collected healthcare data (VSHL) *PI*: Prof Jim Buttery (HREC 79964) The project aims to ensure the continued safety of vaccines administered in Australia using routinely collected electronic health care data from various settings and securely link them	The RCH HREC approved a waiver for data linkage of routinely collected health information from various settings (administrative registers, hospitals, and primary care) to create a large dataset that will enable researchers to analyse a broad spectrum of adverse events to ensure the continued safety of vaccines. The Centre for Victorian Data Linkage (CVDL) will securely house the identifiable data received from the multiple settings, and then convert them

together to create a large and rich dataset that will enable us to analyse a broad spectrum of adverse events which may otherwise go undetected by the current surveillance methods. The project will include all persons who have received a vaccination in Victoria and will aid in maintaining and strengthening community, provider, and health authorities' confidence in vaccinations with the knowledge that vaccine safety is being closely scrutinized and swift policy change can be enacted when safety signals do occur.	into a linked de-identified dataset for analysis. Only this de-identified data will be made available to the research team.
Melbourne Children's Heart Tissue Bank PI: Prof Igor Konstantinov (HREC 38192) The Melbourne Children's Heart Tissue Bank is an established biobank that aims to investigate the genetic causes of childhood heart disease and to develop novel regenerative therapies.	For parents/guardians who have consented to tissue and/or organs taken for autopsy to be retained for future research at the Victorian Perinatal Autopsy Service (VPAS) at the Royal Women's Hospital (RWH). The RCH HREC approved a waiver of consent for that tissue and/or organs to be transferred from VPAS and stored at the MCRI in the Melbourne Children's Heart Tissue Bank.