

## Medical Research

## **Future Fund**

MRFF Webinar

15 November 2022

Dr Masha Somi, CEO Health and Medical Research Office Mr Lachlan Lo, Senior Patent Examiner, IP Australia



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## MRFF and Intellectual Property (IP)

- MRFF funds priority driven research with a focus on research translation, including commercialisation
- MRFF, as an Australian Government research funding scheme, supports good management of IP arising from publicly funded research
  - As outlined in The National principles of Intellectual Property management for publicly funded research
- MRFF grant opportunities guidelines include:
  - A request for detail of intellectual property in grant applications or during the grant life (for example Commonwealth commercialisation clauses)
  - Expectation that grantees must ensure appropriate safeguards are in place to protect patient privacy, intellectual property and commercially confidential information when considering dissemination of research outcomes.



See NHMRC.gov.au for more information



### Commonwealth Commercialisation Clauses

- Grant Agreements relating to projects funded under some Grant Opportunities may include commercialisation clauses
  - For example, 2021 BioMedTech Incubator Grant Opportunity, 2021 COVID-19 Treatment Access and Public Health Activities Grant Opportunity and 2021 mRNA Clinical Trial Enabling Infrastructure Grant Opportunity
- The intent of the clauses is to give an early opportunity for the Australian Government to purchase commercialised products (at market conditions) where research has had MRFF support
- As stated in the National principles:
  - good intellectual property management will foster the most beneficial use of Australian research and development to secure value for industries, government, researchers and the community.





# Mr Lachlan Lo Senior Patent Examiner





# How Intellectual Property (IP) can make your research a success

Lachlan Lo
Senior Patent Examiner at IP Australia

November, 2022











## **INTELLECTUAL PROPERTY**

- Intellectual property, or IP, refers to a range of different, legally enforceable rights that arise from the new ideas you create
- The property of your mind or exclusive knowledge
- Australia's IP laws provide a legal framework to protect your creative ideas through IP rights.











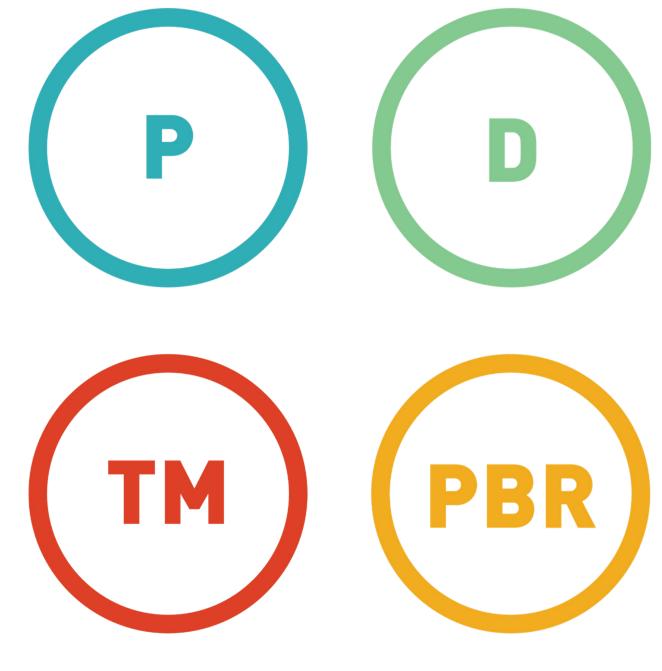
## **INTELLECTUAL PROPERTY**

#### Registered rights administered by IP Australia:

- Patents
- Trade marks
- Designs
- Plant breeders rights.

#### **Unregistered rights:**

- Copyright
- Trade secrets
- Circuit layouts.













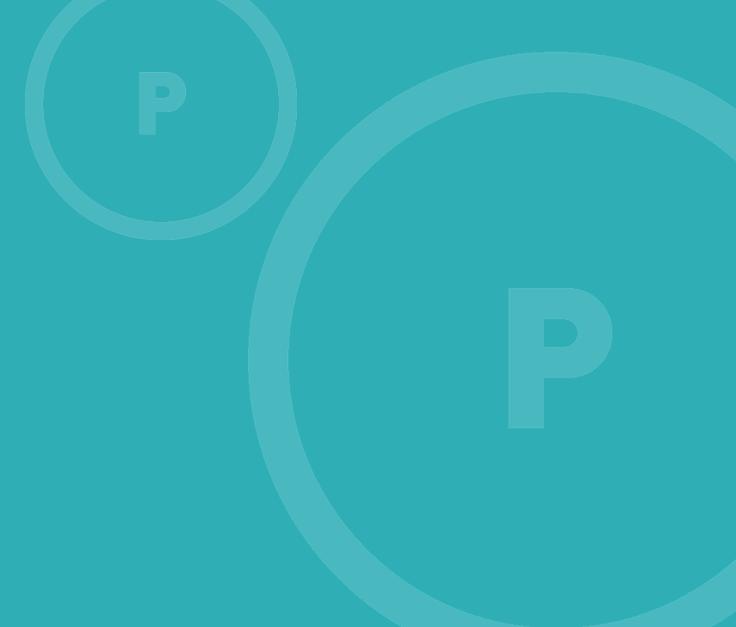












## **PATENTS**

- A legally enforceable right for a device, substance, method or process
- Must be new, inventive and useful.

#### **Life span of patents:**

- Standard up to 20 years
- Pharmaceutical up to 25 years.











# PATENT STATISTICS (2021)

- **37,397** Australian patent filings
- **9%** were Australian applicants
- **11%** increase in filings from 2020
- **94%** filed by organisations, **6%** filed by individuals.











## **BENEFITS OF PATENTS**

#### **Rights holders:**

- Exclusive right to commercially exploit the invention
- Prevent others from infringing
- Block competition
- License the patent as a revenue stream
- Can sell the patent
- Can attract investors and help secure research funding.

#### The public:

- Detailed description of the invention is disclosed
- Contributes to the scientific knowledge of the tech area
- Encourages R&D of new and innovative products
- Accelerates and advances technological development.









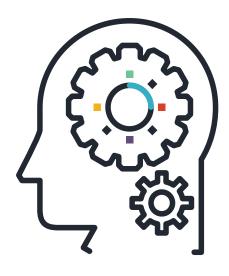


## FOR AN IDEA TO BE PATENTABLE:





Needs to be different to anything done before



2. It must be INVENTIVE

Must go beyond what is obvious given the normal progress of technology



#### 3. It must be USEFUL

Has a specific, credible and substantial use









## WHAT CAN BE PATENTED

 A device is usually protected by a group of patents relating to different aspects.

## For example, a heart monitor can be covered by patents relating to:

- User interface
- Software
- Battery
- Memory
- Power management system
- Integrated circuits
- Wireless or internet connectivity











## WHAT CAN'T BE PATENTED

- Human beings or the biological process for their generation
- Artistic creations
- Mathematical models
- Plans, schemes or other purely mental processes.

#### **Each country has different requirements:**

• E.g. You can patent methods of surgery and medical treatments in the US and Australia, but not in Europe or Japan.











## IP MANAGEMENT IN COLLABORATION

- Protecting your IP is just the first step in commercialising your idea.
- Collaboration between researchers and business is a key element of successful innovation.
- Collaborations can involve complexity in managing the interrelationships between confidentiality, use of existing IP, publication of information, commercialisation, decision making around IP rights.
- Consideration and management of IP at the outset can help to prevent delays and avoid IP disputes as the project progresses.











## **COMMERCIALISE YOUR IP**

The following tools can assist:

**Australian IP Toolkit** - designed to facilitate, simplify and improve collaboration between researchers and industry – template contracts, agreements, guides and checklists.

**Source IP** – a digital marketplace helping businesses and researchers connect and collaborate.

**Small business portal** – helping business navigate the IP system.

**Patents Case Management for SMEs - c**onnects you with a dedicated IP Australia subject matter expert who is your single point of contact to assist you at any stage of the process.

**Patent Analytics Hub** - translates patent literature to help government and publicly funded research organisations make informed research, development, collaboration and commercialisation decisions.

**Engaging an attorney toolkit** - equip small and early stage business with the tools they need to have more informed conversations with the attorney profession.



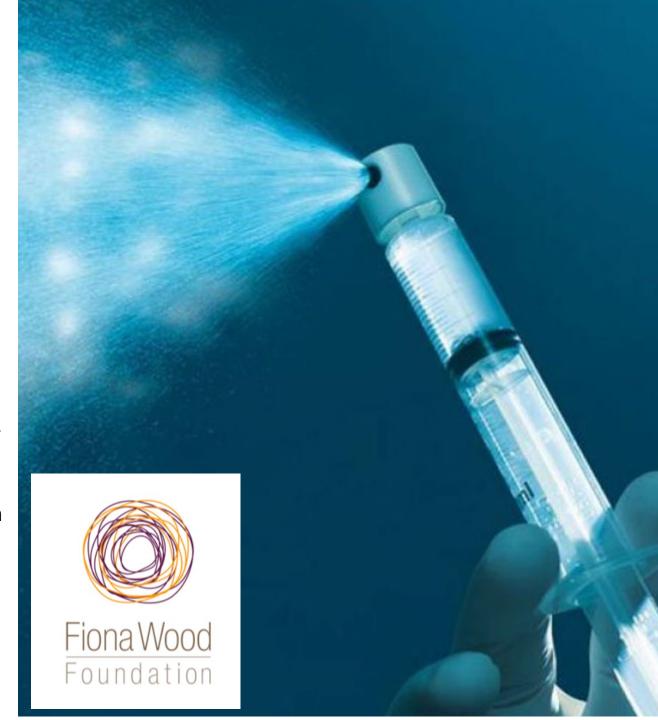






## CASE STUDY: RECELL SPRAY-ON SKIN

- In 1999, Perth-based plastic surgeon Professor Fiona Wood patented her skin repair technique
- Uses burn victim's healthy skin to grow new skin cells in a lab
- Reduced time to grow skins cells to cover extensive burns from 21 days to 5 days (now only 30mins)
- Key role in treating burns victims from 2002 Bali bombings, saving 28 lives
- A foundation was established by Professor Wood
- Royalties from licensing of her IP is used to fund further research, education and innovation
- The 'spray-on skin' technology commercialised through Clinical Cell Culture Pty Ltd (now AvitaMedical) has been used on more than 10,000 patients around the world.











## **SEARCHING PATENTS**

Before you apply for a patent, it's important to conduct a comprehensive search.

#### Why you should search

Before introducing a new product to the market, you need to ask yourself two things:

- Can I protect my invention with a patent?
- Does my invention infringe someone else's patent?

Searching can help answer these questions:

- determine who owns what IP
- check that your IP is not being infringed
- obtain product information on your competitors for research purposes.











## **PATENT SEARCHING**













## **GOOGLE PATENTS**



total artificial heart







Include non-patent literature (Google Scholar)

Search and read the full text of patents from around the world.









## **PATENT ATTORNEYS**

It's recommended that you seek professional assistance before applying for a patent

#### **Patent attorneys:**

- Provide advice regarding patenting and IP
- Help to prepare and file Patent Applications
- Provide representation in Patent oppositions
- Provide advice in relation to Patent infringement.











## **DISCLOSURE**

#### **BEWARE:** Don't go public too soon

 Don't demonstrate, sell or discuss your invention in public before filing an application

## **Confidentiality or Non-Disclosure Agreements** (NDAs)

 Legal contract to ensure that a person who gains access to sensitive information doesn't disclose it to a third party











### THE APPLICATION PROCESS

## **Provisional application**

- Gives you 12 months to decide if you wish to file a complete application
- Does not give you patent protection

## **Complete application**

- Is necessary for patent protection
- Gives you the right to take legal action against others using your invention in Australia without your permission









## **PROTECTION**

An Australian patent does not give you protection outside of Australia.

## For overseas patent protection, you have two choices:

- 1. Apply separately to each country
- 2. Apply through WIPO's international Patent Cooperation Treaty system.













## **COSTS**

International	\$ AU	Standard	\$ AU
Provisional patent	110	Provisional patent	110
PCT filing and search fee	4,370	-	
National phase entry fee	370	Patent application fee	370
Exam request fee	490	Exam request fee	490
Acceptance fees	250	Acceptance fee	250
4տ year anniversary fee	300	4th year anniversary fee	300
Total	5,890	Total	1,520

Note: Annual renewal fees required to keep the patent "alive"

Fees quoted assume online filing

There are additional – optional – steps in the process that incur fees

Fees will apply for each jurisdiction you seek a patent

Attorney fees not included







## **ENFORCEMENT**

If you find your invention is being copied or used by someone else without your permission, it is up to you to take action against them.

IP Australia does not police IP rights or launch legal proceedings on your behalf.













# **Spotlight: The medical device market**











## **EXAMPLES OF MEDICAL DEVICES**

- Neurostimulators
- Tissue engineering bioreactors
- Diagnostic instruments
- Syringes, catheters, probes
- Prostheses
- Respiratory devices
- Medical imaging devices
- Patient monitoring
- Implantable devices
- Surgical equipment
- Disposable medical supplies, etc.

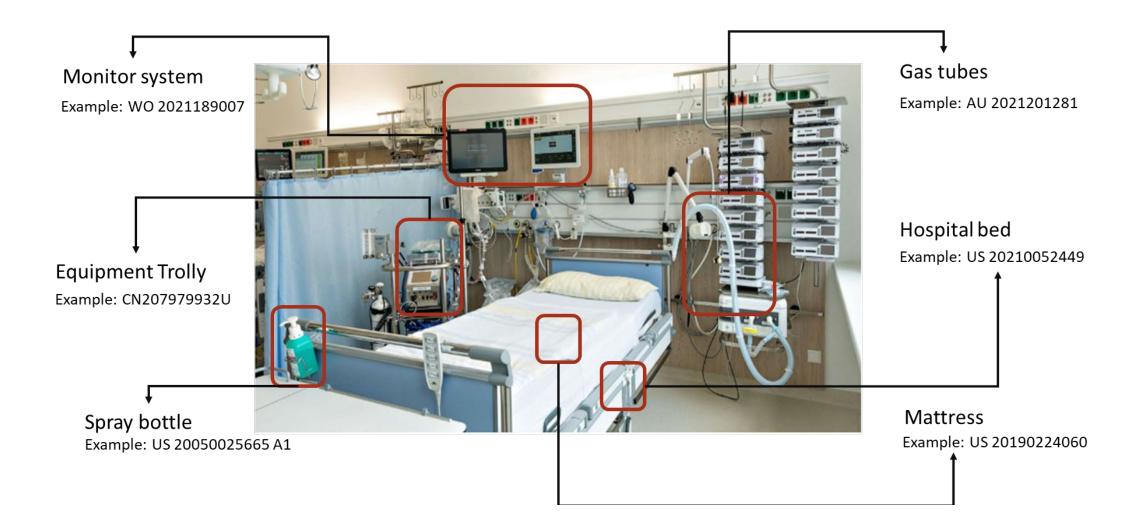












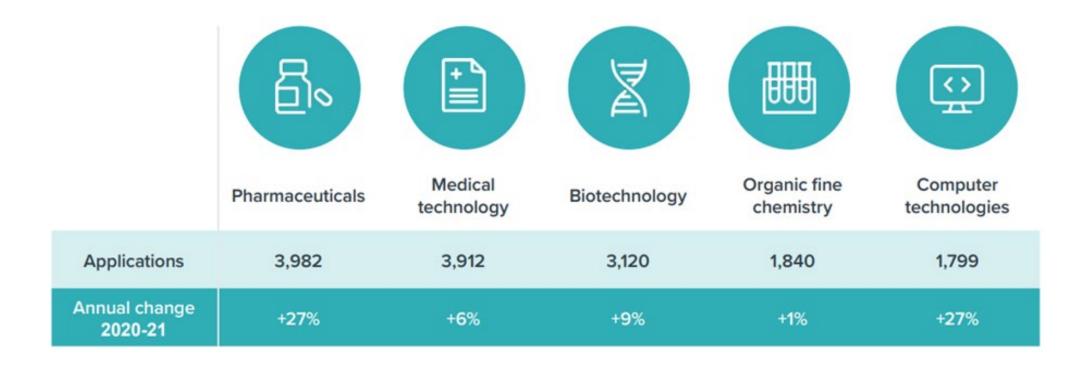








## STANDARD PATENT APPLICATIONS IN AUSTRALIA (2021)









# TOP DOMESTIC PATENT APPLICANTS IN AUSTRALIA (2021)

Top domestic applicants			
Rank	Applicant	Total applications	
1	Aristocrat Technologies Australia Pty Ltd	71	
2	Commonwealth Scientific and Industrial Research Organisation	52	
3	NewSouth Innovations Pty Ltd	29	
4	ResMed Ltd	28	
5	Breville Pty Ltd	27	









## **KEY REGIONS FOR MEDICAL DEVICE PATENTS**









## **IMPORTANT TAKEAWAYS**

- Consider IP management early
- When you register your IP, it will be published online
- Your invention needs to be a secret until you apply
- You will need to consider what countries you want to seek protection in
- Visit ipaustralia.gov.au to search, read case studies, and find checklists, guides and toolkits
- Seek professional advice.











### **EDUCATION AND RESOURCES**

IP Australia website: ipaustralia.gov.au





#### **Case studies**

https://www.ipaustralia.gov.au/toolsresources/case-studies









#### Choosing the right IP

https://www.ipaustralia.gov.au/tools-resources/choosing-right-ip





## Short videos answering FAQs

https://www.youtube.com/watch?v=k-3M0lgqNqA





## IP Toolkit for collaboration

https://www.ipaustralia.gov.au/tools-resources/ip-toolkit





#### **On-demand webinars**

https://www.ipaustralia.gov.au/about-us/newsandcommunity/webinars?keys=&field\_webinars\_topic\_tid =1211





#### **Patent Case Manager**

https://www.ipaustralia.gov.au/toolsresources/ip-toolkit









## **EXPORTING, ECONOMIC PAPERS & ANALYTIC REPORTS**

IP Australia website: ipaustralia.gov.au





### **Taking your IP global**

https://www.ipaustralia.gov.au/understanding-ip/taking-your-ip-global





### **Economic papers**

https://www.ipaustralia.gov.au/about-us/researchand-data/office-chief-economist





### **Patent analytics reports**

https://www.ipaustralia.gov.au/about-us/researchand-data/patent-analytics-hub











# Australian Medical Research and Innovation Priorities 2022–2024

2022-2024 Priorities took effect on 6 November 2022.

- Australian Medical Research Advisory Board developed the Priorities concurrently with the Australian Medical Research and Innovation Strategy 2021-26
- The table is a high-level overview of how the MRFF initiatives align with the 2022-24 Priorities
- See: www.legislation.gov.au/Details/F2022L01407

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2022 2024 priorities	21 MRFF initiatives
Consumer Driven Research	<ul> <li>Emerging Priorities and Consumer-Driven Research</li> <li>Preventive and Public Health Research</li> </ul>
Research Infrastructure and Capability	<ul> <li>National Critical Research Infrastructure</li> <li>Research Data Infrastructure</li> <li>Clinician Researchers</li> <li>Researcher Exchange and Development within Industry</li> </ul>
Translation and Commercialisation	<ul> <li>Medical Research Commercialisation</li> <li>Frontier Health and Medical Research</li> <li>Genomics Health Futures Mission</li> <li>Stem Cell Therapies Mission</li> <li>Cardiovascular Health Mission</li> <li>Rapid Applied Research Translation</li> <li>Early to Mid-Career Researchers</li> <li>Million Minds Mental Health Research Mission</li> </ul>
Comparative Effectiveness	Clinical Trials Activity
Research	Preventive and Public Health Research     Preventive and Public Health Research
Preventive and Public Health Research	<ul> <li>Million Minds Mental Health Research Mission</li> <li>Cardiovascular Health Mission</li> </ul>
Primary Care Research	Primary Health Care Research
Health and Medical Researcher Capacity and Capability	<ul> <li>Clinician Researchers</li> <li>Early to Mid-Career Researchers</li> <li>Researcher Exchange and Development within Industry</li> </ul>
Aboriginal and Torres Strait Islander Health	Indigenous Health Research Fund
Priority Populations	<ul> <li>Dementia, Ageing and Aged Care Mission</li> <li>Clinical Trials Activity</li> <li>Australian Brain Cancer Mission</li> <li>Traumatic Brain Injury Mission</li> <li>Million Minds Mental Health Research Mission</li> </ul>
Antimicrobial Resistance	Global Health
Global Health and Health Security	Global Health
Health Impacts from Environmental Factors	Emerging Priorities and Consumer-Driven Research
Data, Digital Health and Artificial	National Critical Research Infrastructure
Intelligence	Research Data Infrastructure



# Program Focus: MRFF Consumer Reference Panel (CRP)

#### 2015-2021

Some practices & processes in place to encourage consumer engagement in the MRFF

...but we want to do more...



# Established the MRFF Consumer Reference Panel

"to provide advice to the CEO of HMRO on strategies for strengthening consumer involvement in MRFF implementation"

#### 2022-onwards

Work with the CRP to strengthen consumer involvement in the MRFF

#### Initial deliverables:

- Developing principles for consumer involvement in MRFF-funded research projects
- Reviewing and providing advice on MRFF processes, e.g. grant guidelines, assessment processes



# Program Focus: Refresh of Assessment Criteria

- Refinement of descriptors for the four criteria that are used to assess applications to MRFF grant opportunities
- The key changes to the assessment criteria descriptors include:
  - reducing the number of descriptive dot points to assist applicants and assessors
  - using simpler language to clearly draw out the elements to be assessed
  - incorporating specific expectations for research focusing on priority populations
  - including more explicit expectations for consumer involvement.
- Will be implemented across new MRFF grant opportunities
- Department will provide guidance and support to grant assessment committee members
- More information at: <a href="https://www.health.gov.au/resources/publications/refresh-of-the-medical-research-future-fund-assessment-criteria-october-2022">www.health.gov.au/resources/publications/refresh-of-the-medical-research-future-fund-assessment-criteria-october-2022</a>



### Next steps

- Strengthening the involvement and representation of priority populations in the MRFF
  - integrate diverse voices and experiences into the design and assessment of MRFF granting activities.
  - initially, further strengthen inclusion of the unique knowledge and experiences of First Nations people on grant assessment committees.
- Seeking expressions of interest to join MRFF grant assessment committees
  - researchers with expertise in priority populations
  - individuals from priority population groups to join MRFF grant assessment committees.
  - <u>www.nhmrc.gov.au</u> and search 'MRFF Grant Assessment Committee'
- Thank you to all members of the grant assessment committees.
  - The MRFF Roll of Honour has been published acknowledging the people who participated in MRFF grant assessments between 1 July 2021 and 30 June 2022.



### Initiative Focus: Million Minds Mental Health Research Mission

- Innovative mental health research to support a million Australians with mental health issues with access to new approaches to prevention, diagnosis, treatment and recovery
  - \$125 million from 2018-19 to 2027-28
- To date, \$64.8 million has been awarded for 18 mental health research grants
  - Eating disorders (2 projects)
  - Mental health of children and young people (2 projects)
  - Mental health of First Nations Peoples (3 projects)
  - Suicide prevention (3 projects)
  - COVID-19 Mental Health Research (6 projects)
  - Establishment of mental health Clinical Trials Networks (2 projects)



### Review of the Million Minds Mental Health Research Mission

- The MRFF Monitoring, Evaluation and Learning Strategy 2020-21 to 2023-24, states that regular reviews are to be undertaken of the MRFF initiatives
- University of Technology Sydney was contracted to undertake a review of the Mission and the review report was published on 28 October.
  - The independent review found investments align with the Mission's existing Roadmap and progress towards the MRFF Measures of Success and Impact Measures
  - The report listed opportunities for the Mission including investing in research in high burden of disease topics and high risk groups, understanding the variety of factors influencing mental illness, and integrative approaches for improving mental health such as interdisciplinary approaches and community involvement
- The Mission's Expert Advisory Panel considered the opportunities identified in the review report during the development of the Mission's Roadmap and Implementation Plan





### Consultation on the Mission's draft Roadmap and Implementation Plan

The Mission's second Expert Advisory Panel (EAP) was appointed in April 2022

Prof. Maree Teesson AC (Chair) Prof. Susan Cotton

A/Prof. Yvonne Cadet-James Prof. Ian Everall

Ms Shannon Calvert Prof. Jennifer Hudson

Prof. Helen Christensen AO Prof. Lorna Moxham

- The EAP is revising the Roadmap and developing an Implementation Plan for the Mission
- The consultation to seek feedback from the community on the Mission's draft Roadmap and Implementation Plan opened on 28 October and closes 1 December



**Prof. Maree Teesson AC (Chair)** 

Visit: consultations.health.gov.au



### **MRFF Innovation Grants**

- These grants
  - o allow grantees to build evidence of the feasibility of their projects to be competitive in future
  - o aimed to support capacity building for specific groups of researchers (eg First Nations researchers)
  - o small scale (\$200,000) and short-term (6-12 months) funding
- In making a recommendation for an Innovation grant, the Grant Assessment Committee will consider an Innovation Grant pitch in the application
- Innovation grants have been awarded in
  - 2021 Improving the Health and Wellbeing of Aboriginal and Torres Strait Islander Mothers and Babies Grant
     Opportunity
  - 2021 Dementia, Ageing and Aged Care Grant Opportunity



# MRFF Program updates

- MRFF Grant Variation Policy (published May 2022)
- Policy Statement for Department of Health and Aged Care Staff Participating in Activities Funded by MRFF (published March 2022)
- Continue work with Business Grants Hub on the Business Grants
   Management system for MRFF grant applications
- MRFF Monitoring, Evaluation and Learning Strategy 2020-2021 to 2023-2024 sets out the principles and approach used to monitor and evaluate the MRFF
  - Current evaluation of initiatives: Australian Brain Cancer Mission and Clinical Trials Activity Initiative
  - A stakeholder consultation phase on the Australian Brain Cancer Mission is planned
- Currently Performance Indicators for the MRFF Measures of Success are being developed; more information will be available in 2023



#### Medical Research Future Fund Grant Variation Policy

MRFF grants are awarded following rigorous review of applications for funding and are managed by the Department of Health in partnership with grant hubs, including the Business Grants Hub (BGH) and the National Health and Medical Research Council (NHMRC).

MRFF grant funds may only be used to conduct agreed activities as specified in the grant agreement and must not be used for any other purposes without the prior written approval of the Program Delegate. The organisation administering the grant (administering organisation) must ensure that the grant activity is conducted in accordance with the grant agreement.

A grant variation is required when there are or will be changes to the grant agreement. This policy provides an overview of the types of variations that can be requested for an MRFF grant and the circumstances in which they may apply. Research Administration Officers (or equivalent; henceforth referred to as RAO) and Grantees should also review the grant opportunity guidelines under which a grant was awarded to determine eligibility and variation requirements.

MRFF grant funds must be used for the purpose outlined in the original approval. Variations can neither be used to request an increase of MRFF grant funds nor to request changes that do not align with the purpose of the grant outlined in the respective grant opportunity muldelines.

RAOs and Grantees should note that variation requests involving the movement of MRFF funds across financial years may not be possible without loss of some grant funding, depending on the availability of funds to accommodate the revised payment schedule in the relevant financial years.

Where the circumstances for a variation request do not match those listed in this policy, researchers must first consult with their RAO who may then contact the relevant grant hub for clarification. Researchers must not approach the grant hub or the Department of Health directly for advice on how to manage variations.

The decision to approve or reject a variation request is at the sole discretion of the Program Delegate. Note, once approved, information pertaining to the grant variation may be published online.

For further information regarding the process for submitting requests for variations, including required evidence, see **Hub Resources and Contacts** at the end of this document.

#### Types of Variations

#### 1. Defer grant commencement date

This type of variation can be used to request a deferral to the commencement date of a grant, provided that the commencement date has not passed, and grant payments have not yet commenced.

Circumstances where this may apply include:

- where organisational approvals needed at the commencement date are not in place
   where the Chief Investigator A/Project Lead has an existing contractual obligation that
- cannot be met in time to meet the commencement date

Version 1.2022

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## MRFF Communications updates

- Inaugural MRFF RAO Webinar is available on the MRFF website
- MRFF Projects
  - Stories for the general public to read about projects funded by MRFF
  - Recently published
    - Reducing the high rate of chronic kidney disease in First Nations communities (Kim Morey, Co-Theme Leader of Wardliparingga Aboriginal Health Equity, South Australian Health and Medical Research Institute)
    - Supporting bushfire responders after the fires (Dr David Lawrence, University of Western Australia)
- Newsletter will announce the opening of Grant Opportunities
  - Subscribe to the newsletter at the MRFF website
  - Register with GrantConnect to also receive notifications when new opportunities open.



#### 24 October 2022

Announcemen

Welcome to this Medical Research Future Fund (MRFF) announcement.



### \$86 million for genomic, data infrastructure, and treatment and intervention research

Researchers are invited to apply for the following MRFF grant funding

- up to \$66 million under the <u>2022 Genomics Health Futures Mission grant opportunity</u>. Application close 22 February 2023.
- up to \$10 million under the 2022 Research Data Infrastructure grant opportunity. Up to a further \$10 million will also be available through Research Data Infrastructure grant opportunities in both 2023 and 2024. Applications for the 2022 grant opportunity open on 2 November 2022 and close 43 Extract 2020.
- up to \$10 million under the <u>2022 Assessment of High-Cost Gene Treatments and Digital Health Interventions grant opportunity</u>. Applications close 1 March 2023.

All MRFF grant opportunities are advertised on GrantConnec

 $\label{eq:Registerwith Grant Connect} \ \text{to receive notifications when new opportunities open}.$ 



### What else?

- Let us know your concerns so we can act on them
- Give us your great ideas
  - What would a great grant opportunity, process etc look like?
- Strengthened focus on **consumer involvement** 
  - What relationships can you build on?
- Contribute to consultations
  - Million Minds Mental Health Mission by 1 December



### What else contd.?

- Encourage you to get informed
  - MRFF newsletter, webinars, webpages, Twitter, LinkedIn
- To feature in **announcements/media/events** 
  - Encourage researchers to write easily understandable, engaging media summaries
  - Tell us about your projects for features on the MRFF Projects webpage
- Encourage you to nominate for a Grant Assessment Committee
  - <a href="https://www.nhmrc.gov.au/2021-22-medical-research-future-fund-mrff-grant-opportunities">https://www.nhmrc.gov.au/2021-22-medical-research-future-fund-mrff-grant-opportunities</a>



# A&D





## Continuous feedback loops...we are listening and learning

- Receive feedback via AMRAB and other consultation processes
- Seek and receive feedback from sector, including through structured processes
- Observing which grant opportunities generate most interest
- Identifying gaps in funding opportunities
- Scanning the environment for emerging issues/unmet needs





## **Keep Connected**





# Thank you for your time