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Thursday, 12 January 2017

Mr Tim Kelsey
Chief Executive
Australian Digital Health Agency
Level 25
56 Pitt St
Sydney NSW 2000

Dear Mr Kelsey

CONSULTATION TO DEVELOP THE NATIONAL DIGITAL HEALTH STRATEGY

Thank you for your letter of 3 November 2016 to Professor Aidan Byrne, inviting the Australian Research Council (ARC) to provide input to inform development and delivery of a National Digital Health Strategy (NDHS). Professor Byrne recently left the ARC and I am currently acting ARC Chief Executive Officer.

The following response provides information on the ARC's role in supporting (i) health and medical research (including research relevant to digital health), and (ii) the development of research partnerships between universities and other organisations including industry.

The Australian Research Council

The ARC is a Commonwealth entity within the Australian Government. It funds research and researchers under the National Competitive Grants Program (NCGP) which consists of two elements—Discovery and Linkage. Within these elements are a range of schemes structured to provide a pathway of incentives for researchers to build the scope and scale of their work and collaborative partnerships. Funding decisions under the NCGP are made on the basis of a competitive peer review process.

The ARC also evaluates the quality of research being undertaken in higher education institutions through Excellence in Research for Australia (ERA). ERA is aimed at identifying research excellence in Australian higher education institutions by comparing Australia's research effort against international benchmarks. ERA assesses quality using a combination of indicators and expert review by research evaluation committees.

In December 2015 as part of the *National Innovation and Science Agenda* (NISA) the Australian Government announced the development of a national engagement and impact assessment which will examine how universities are translating their research into economic, social and other benefits. The ARC will implement this assessment which will run as a companion to ERA.

ARC support for digital health research

The ARC funds research across all disciplines through its NCGP, although it does not normally fund health and medical research for which the National Health and Medical Research Council (NHMRC) is responsible. This means that ARC-funded research extends

from all of the STEM–Science, Technology, Engineering and Mathematics–fields to all of the fields encompassed by the humanities, arts and social sciences.

Digital health research falls within the areas of research funded by the ARC to the extent that it (i) meets the criteria of eligible research articulated in the *ARC's Medical Research Policy* (see **Attachment A**); or (ii) falls within the areas of engineering and information and computing sciences.

Relevant projects are funded under both the Discovery and Linkage Programs of the NCGP. The Discovery Program recognises the importance of building a strong capability in fundamental research, while the Linkage Program aims to encourage and extend cooperative approaches to research by promoting national and international research partnerships between researchers and business, industry, community organisations and other publicly funded research agencies.

Support for the development of research partnerships

Page 6 of the discussion paper poses the question '*How can the science, research and teaching community better partner with industry to develop digital health solutions that support individuals and healthcare providers?*'

The ARC's Linkage Program, particularly the *Linkage Projects* scheme, is one way that university researchers can seek support to partner with industry, or other organisations, to encourage the transfer of skills, knowledge and ideas as a basis for securing commercial and other benefits of research.

The *Linkage Projects* scheme has been in place since 2002, and in that time has established itself as an important component of the university research funding landscape. University researchers are able to work on real time problems, while industry or end-user researchers are able to access knowledge, skills and facilities that may not be available to them. Over 90 per cent of partner organisations indicate that the partnership supported through a *Linkage Projects* grant has been beneficial or very beneficial—a number of them also go on to develop sustained relationships with particular groups of university researchers.

In *Linkage Projects* selection rounds conducted since 2010, funded projects include research into:

- managing knowledge in telehealth projects (LP110100671)
- predictive analytics from at home telemonitoring of vital signs (LP160101202)
- engineering the convergence of telecare and telehealth (LP130100159)
- Med Graphic Avatar (LP1102001660)
- a youth mobile help seeking tool (LP 150100178)
- e-health communication strategy and design (LP110100405).

The partner organisations on these projects include hospitals, state health departments, as well as industry organisations.

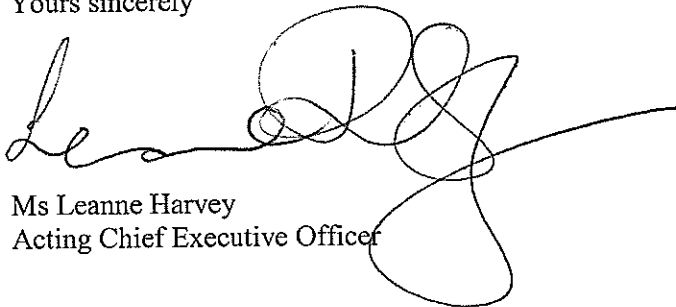
One of the ARC's more recent schemes, the Industrial Transformation Research Program (ITRP) is aligned with the priorities of the Australian Government's Industry Growth Centres initiative, one of which is currently Medical Technologies and Pharmaceuticals (previously Medical Devices and Biotechnology). Under the ITRP, which comprises research hubs and training centres, universities partner with other organisations including industry to conduct cutting edge research on new technologies, supporting the development of research capability in the identified priority areas.

Since the ITRP commenced in 2012, five selection rounds have involved either Medical Devices and Biotechnology or Medical Technologies and Pharmaceuticals as priority areas. Centres and Hubs subsequently established under these priorities include:

- ARC Research Hub for Advanced Manufacturing of Personalised Medical Devices
- ARC Research Hub for Integrated Device for End-user Analysis at Low-levels
- ARC Training Centre in Additive Biomanufacturing
- ARC Training Centre for Biopharmaceutical Innovation
- ARC Research Hub for Graphene Enabled Industry Transformation.

I hope this information is useful. If you would like additional information about the ARC's funding schemes, please do not hesitate to contact us.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Leanne Harvey', with a long horizontal line extending to the right.

Ms Leanne Harvey
Acting Chief Executive Officer

ARC Medical Research Policy

The ARC may fund health and medical research, either in concert with the National Health and Medical Research Council (NHMRC) or directly, to address specific Australian Government health and medical research priorities, however, the ARC does not normally fund health and medical research through its competitive funding schemes.

There are research activities that potentially intersect with both ARC and NHMRC responsibilities. To provide clarity to potential applicants, this policy details the research at this juncture that would be eligible for ARC support. This is intended to reduce the likelihood of applicants preparing and submitting ineligible proposals to the ARC. The ARC remains committed to ensuring that there is no eligibility 'gap' between the two agencies (in terms of disciplines or fields of research).

Those seeking funding for health and medical research should explore options available through the NHMRC which considers applications in any area relevant to human health, or other health and medical research funding organisations.

1. **Research eligible¹ for ARC support:**

- a. research in bioengineering, where the goal is to advance engineering knowledge by applying engineering principles to problems that may ultimately have medical applications; or,
- b. research in the natural sciences, where the goal is the fundamental understanding of biological processes or the development of knowledge and/or technology platforms, that may ultimately have medical applications; or,
- c. research (including observational research) where the goal is the understanding of normal human life stages (e.g. infancy, childhood, adolescence and ageing) and/or traits using human participants or populations, unless it involves a health intervention; or,
- d. the use or development of equipment, facilities, tools, games, devices, smart phone applications or other items to support eligible research as listed above.

2. **Research ineligible for ARC support:**

- a. research with human health and/or medical goals, including research on the understanding, aetiology, diagnosis, monitoring, management or treatment of physical or mental disease or other health conditions in humans; or,
- b. research involving the use or development of animal models of human health conditions, or the use of animals for the development or testing of therapeutic goods (including devices) or procedures, for the purpose of better understanding human health or developing treatments for human health conditions; or,
- c. interventional research in humans, particularly clinical or pre-clinical trials of therapeutic goods (including devices), or research aiming to modify the health of the human participants; or,
- d. the use or development of equipment, facilities, tools, games, devices, smart phone applications or other items to understand, diagnose, monitor, manage or treat human health conditions.

The ARC may seek further advice from the Office of NHMRC, the Administering Organisation or any other relevant party when determining the eligibility of a proposal.

If the ARC determines that a proposal is at risk of not being considered by either agency (ARC or NHMRC), the ARC reserves the right to deem such a proposal eligible² for assessment.

Recognising that an integrated research project or program may sometimes include a small element of research not supported under this policy, the ARC may, but is not obliged to, deem such a proposal **eligible**³ for assessment provided the proposal predominantly comprises **eligible** research as set out in this policy.

Proposals deemed **ineligible** cannot be recommended or approved for funding under the *Australian Research Council Act 2001*.

Definitions

Disease—Any deviation or interruption of the normal structure or function of any part, organ or system (or combination thereof) of the body that is manifested by a characteristic set of symptoms and signs and whose aetiology, pathology and prognosis may be known or unknown.

Human health conditions—Pertaining to diseases (as defined above), syndromes, pathological conditions, injuries, signs, symptoms, problems and/or conditions that generally lead to contact with, or utilisation of, health services.

Intervention/al—Includes interventions designed to understand and/or change human health conditions, such as:

- clinical or pre-clinical trials in human participants
- the collection and/or use of body organs, tissues or fluids e.g. skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens or exhaled breath
- behavioural interventions
- dietary interventions.

Medical research—Includes medical and/or dental research.

Therapeutic Goods; Therapeutic use—As defined in the *Therapeutic Goods Administration Act (1989)* incorporating all updates as at the date of the publication of this policy.

¹ Eligible under the *ARC Medical Research Policy*; other research not covered by this policy may also be eligible for ARC support.

² Subject to all other eligibility requirements set out in the relevant funding rules also being met.

³ *Ibid.*