Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

17 August 2020

Mike Dawes
CEO
The Key to Life Charitable Trust

By email: [redacted]

Tēnā koe Mr Dawes

Complaint: [redacted]
Our ref: **E20/01403/AJA**

I write further to Alexia Kapranos' letter of 2 March 2020.

I have now had the opportunity to carefully consider all the information collected as part of this Office's assessment of [redacted] letter (on behalf of a collective of suicide attempt survivors and bereaved whānau) relating to the 1000 Letters Project (the Study) undertaken by the Key to Life Charitable Trust (the Trust). This included your email of 6 December 2019 and your response of 7 March 2020, and subsequent information and comments from Mr King, the Trust's Founder.

I have previously told you that I consider the research conducted in the Study to broadly constitute health research under the Code of Health and Disability Services Consumers' Rights (the Code). After further consideration, I am mindful of jurisdictional hurdles in applying the Code to deceased consumers, observational research and the use of health information. I have therefore decided that the best way of dealing with [redacted] concerns is to take an educational approach, rather than progressing [redacted] letter as a complaint for the purposes of the Health and Disability Commissioner Act 1994 (the Act).

I understand that the Trust intends the Study to continue. Although I have requested a copy of the Trust's report and protocol, the report has not been provided to me. I also asked when the protocol was written and for the names and qualifications of the researchers but that information also has not been supplied.

I therefore offer suggestions to the Trust, under section 14(1)(i) of the Act, about how the Trust can best ensure it protects the rights of health and disability services consumers, including participants of health research, in the future. In my view, the key considerations are the need to ensure that:

- ethical approval has been obtained where appropriate;
- informed consent has been obtained from participants; and
- the protocol contains a safety plan that includes appropriate referrals of living participants to a health service.

Ethics approval (Right 4(2) and Right 6(1)(d))

Under Right 4(2) of the Code, every consumer has the right to have services provided that comply with professional, ethical, and other relevant standards. In addition, under Right 6(1) of the Code, the right to be fully informed, every consumer has the right to the information that a reasonable consumer would expect to receive, including notification of any proposed participation in research, including whether the research requires and has received ethical approval.

As stated by Rob McHawk from the Ministry of Health ethics secretariat, there is no legal requirement to obtain ethical approval of health and disability research. However, the National Ethical Standards for Health and Disability Research and Quality Improvement[1] (the NEAC guidelines) provide that researchers must meet relevant ethical standards when they undertake health and disability research in New Zealand, irrespective of whether their work requires ethical review.

Ethical approval from an approved ethics committee is required in a variety of circumstances including:

- to provide coverage of participants in a clinical trial who sustain injury, under the Accident Compensation Act 2001
- to allow use and disclosure of health information for research purposes where it is either not desirable or not practicable to obtain authorisation from the individual concerned under the Health Information Privacy Code 1994 (HIPC)
- for every application approved for funding by the Health Research Council (HRC)

The ethical standards applicable to health and disability research are set out in the NEAC guidelines. The role of the health and disability ethics committees (HDECs) is to check ethical issues arising from research to ensure that health and disability research meets or exceeds established ethical standards. One aspect of the role of the HDECs is to ensure that consultation with Māori has been carried out in accordance with the HRC's *Guidelines for researchers on health research involving Māori*[2]. In my view, before the collection of letters commenced, consultation with Māori should have occurred and been documented.

The HDEC's standard operating procedure (SOPs) provide that health and disability research requires HDEC review if it involves human participants recruited in their capacity as consumers of health or disability support services or relatives or caregivers of consumers of health or disability support services. The SOPs state that some research does not require HDEC review including "observational studies that do not involve more than minimal risk".

The SOP provides that an observational study always involves more than minimal risk if it involves participants who will not have given informed consent to participate; participants who are vulnerable; or the disclosure of health information without authorisation.

Given that at least some of the participants in the Study were vulnerable, it would seem that this research should have undergone ethical review. Accordingly, I suggest that the Trust consult with the Ministry of Health regarding ethical review and oversight of the research before the report is finalised or released.

Information about health research (Right 6 of the Code)

Under Right 6(1)(10) participants have a right to be notified of any proposed participation in research and, under Right(6)(3), the results of the research if they request the information. As noted above, consumers also have the right to the information that a reasonable consumer in that consumer's circumstances would expect to receive including information required by legal, professional, ethical, and other relevant standards (Right 6).

The HDEC website contains templates and forms for a participant information sheet that describe the information that should be given to consumers who are participating in health research. The template sets out a wide range of information including:

- what participation in the Study will involve;

[1] https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement
[2] https://www.hrc.govt.nz/resources/guidelines-researchers-health-research-involving-maori

- the possible benefits and risks of the Study;
- who is paying for the Study;
- what will happen if something goes wrong;
- what are the participants' rights;
- how data will be managed and who will have access to it; and
- how to obtain further information about the Study.

The NEAC guidelines also set out examples of information that should be provided.[3]

Informed consent (Right 7 of the Code)

Under Right 7 of the Code, services (including participation in health research) may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. Right 7(6) outlines that informed consent[4] must be in writing if the consumer is to participate in any research.

Living participants in the Study would need to provide informed consent on their own behalf. In my view, the provision of the letters would not equate to informed consent to the research. That would require provision of the type of information required in the HDEC website to the participants and the participants then making an informed decision to participate in the Study.

With respect to deceased participants, authorisation to use the letters for research purposes would need to be obtained from the personal representative of the deceased author of the letter. That person may not necessarily be the recipient or holder of the letter.

It does not appear that steps were put in place to ascertain whether the executors or administrators of the estates of deceased persons provided the necessary authorisation. I suggest that the Trust give consideration to obtaining appropriate authorisation before progressing further.

Referrals to health services (Right 4 of the Code)

Right 4 of the Code requires health services, including health research, to be provided with reasonable care and skill and to an appropriate standard. Right 4(5) of the Code gives every consumer the right to co-operation among providers to ensure quality and continuity of services.

As noted above, it is unclear whether the Study includes a referral of living participants to health services (such as mental health services). In my view, the protocol should include a safety plan to ensure protection for vulnerable participants and access to appropriate supports.

Use, storage and disposal of personal and health information

There is considerable overlap in this case between HDC's jurisdiction under the Code, and the Privacy Commissioner's jurisdiction to consider matters relating to the collection, use, storage and disposal of health information. Under Right 4(2) of the Code, the Trust must comply with relevant legal standards, including privacy laws, when conducting health research. I have concerns with the way the

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[3] See p75

[4] Under section 2 of the Health and Disability Commissioner Act, *informed consent, in relation to a health consumer on or in respect of whom there is carried out any health care procedure, means consent to that procedure where that consent—*

(a) is freely given, by the health consumer or, where applicable, by any person who is entitled to consent on that health consumer's behalf; and

(b) is obtained in accordance with such requirements as are prescribed by the Code

Trust has obtained, used and disposed of participants' personal information and will bring those concerns to the Privacy Commissioner's attention.

Final comments

I would like to emphasise that I recognise the positive intent of your Trust "to reverse the population trends of depression and suicide" and acknowledge that you intended the Study to contribute to helping to reduce the incidence of suicide. However, "how" the Study is undertaken, including addressing the important factors detailed above, is as important as "why". I share the concerns expressed by the Privacy Commissioner and the Ministry of Health regarding the process involved in the Study. I am particularly concerned about the potential of the Study to cause harm by the failure to:

- obtain ethical approval of the study given the potential vulnerability of participants;
- provide participants with sufficient information; and
- obtain appropriate informed consent.

Further, I am concerned about the lack of evidence of appropriate safeguards for vulnerable participants.

I suggest that the Trust reflect on my comments before it continues the Study. In particular, it would be prudent for the Trust to obtain legal advice regarding the planned process and advice on research ethics. I also suggest that the researchers:

- Develop a more detailed protocol including a safety plan
- Obtain independent peer review of the protocol
- Prepare patient information sheets by adapting the HDEC template
- Ensure that the process complies with privacy law including the rules in the HIPC
- Undertake and record Māori consultation
- Obtain ethics committee approval preferably by a HDEC
- Ensure all participants are provided with the information sheet and are given sufficient time to determine whether they wish to participate
- Obtain written informed consent from all living participants (if participants are deceased obtain authorisation from their personal representatives)

I intend to bring my concerns to the attention of the Ministry of Health and Privacy Commissioner in accordance with section 59(4) of the Health and Disability Commissioner Act 1994, as I consider it in the public interest for both Offices to be aware of my consideration of this matter. [redacted] Other than that, I will not be considering this matter further.

Thank you for your assistance with this matter.

Nāku iti noa, nā

Kevin Allan
Mental Health Commissioner