Dr Michael Brydon
Chief Executive
The Sydney Children's Hospital Network
Locked Bag 4001
Westmead 2145

17th February 2019

Dear Dr Brydon,

Re: HREC/17/SCHN/164 - Fast Track to Health: The alternate day fasting diet in adolescents with obesity: a randomised controlled trial

I wish to appeal the decision to overrule my complaint to the Sydney Children's Hospitals Network Human Research Ethics Committee (SCHN HREC) regarding the Fast Track to Health trial, dated 5 November 2018.

Since my initial complaint, which was endorsed by 28 health professionals and 2 international organisations, 10 000 people have signed a petition expressing their concern about the ethics of this trial. Signatories include health professionals, eating disorders experts, parents and people with a lived experience of being placed on diet in their adolescence who subsequently developed problems with eating disorders. A key concern raised is that the trial prioritises children's risk of chronic disease, which may not appear until adulthood, over and above their growth and development, mental health, and social well-being.

My complaint was overridden by the HREC in all three expressed areas of concern regarding research merit and integrity, risk of harm, and weight bias. I have attached a copy of my original complaint, and the response from the HREC.

Since I lodged my initial complaint, I have become aware of additional significant issues with the trial and the transparency and objectivity of the SCHN HREC application and complaints process. I am writing to you, as advised by the SCHN executive officer, Ms Asra Gholami, to respectfully request that you review and respond to my original complaint and to the concerns I raise below:

1. Objectivity and transparency of the SCHN HREC

I note that the Chair of the SCHN HREC, Associate Professor Sarah Garnett, is also a chief investigator on the Fast Track Trial. I contacted the SCHN HREC on 15/02/2019 to enquire about the composition of the committee that presided over the original ethics application and my complaint, and was told to contact the Chief Executive Officer of SCHN to obtain this information.

The SCHN HREC Standard Operating Procedures (SOP) states the SCHN subscribes to the ethical standards outlined in the Declaration of Helsinki (DoH). Principle 23 of the DoH under the subheading "Research Ethics Committees" states:

> "23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified..."

In order to provide transparency regarding the SCHN HREC approval of the Fast Track Trial, I request a full copy of the minutes of all HREC committee meetings that discussed and approved the Fast Track Trial, including the review of the complaint I submitted. According to the SCHN HREC SOP 027, the HREC meeting minutes are to include the list of the members present at the meeting while the Fast Track Trial was discussed and any declarations of conflict of interest made at these meetings.

2. Independent Expert Review Panel

I was informed by the HREC Executive Officer, Ms Asra Gholami, that the identities of the independent expert review panel who advised the HREC regarding my complaint could not be disclosed in order to 'respect their privacy and anonymity'. I have been unable to identify a copy of any SCHN policies or procedures in regards to when and how an independent expert panel is convened to discuss complaints against a research trial. I respectfully ask you to provide information on this policy, and if there is not a policy, I request that the expert panel's identity be disclosed to me.

3. Royal Australian College of Physicians Guidelines: Paediatric Policy on the Ethics of Research in Children

The SCHN HREC SOP states that the SCHN subscribes to the ethical standards outlined in the Royal Australian College of Physicians Guidelines (RACP): Paediatric Policy on the Ethics of Research in Children. The RACP guidelines state:

> "In general, research should not be conducted in children where it will expose children to significant risk that exceeds the magnitude and likelihood of potential benefit."

In response to my complaint to the SCHN HREC, Executive Officer Ms Asra Gholami conceded "very restrictive diets such as the Fast Track Trial places adolescents at risk of developing an eating disorder". Eating disorders have a high mortality rate (Arcelus et al., 2011) and are a leading cause of disability among young Australian women (AIHW, 2016) The high rates of morbidity and mortality associated with eating disorders exceed the likelihood of potential benefit from the Fast Track Trial and fail to meet the RACP guidelines.

The RACP guidelines also state:

> "In general research should not be conducted in children where the information can be gained equally well in adult volunteers or where suitable preliminary studies have not been conducted in adults first."

In response to my complaint to the SCHN HREC, Executive Officer Ms Asra Gholami also conceded: "Study documentation and the response from the investigators revealed that

although the investigators state there is evidence that MADF achieved weight loss in adults, they do not claim the losses are long term." This would indicate that the Fast Track Trial is to be conducted on children where long term weight loss trials have been found to be unsuccessful in comparison to standard dieting regimes. The majority of people return to pre-intervention body weight following weight loss achieved through lifestyle interventions according to clinical guidelines for the management of overweight and obesity in adults, children and adolescents (NHMRC, 2013).

4. Informed Consent

The likelihood of weight regain and the mental and physical health risks associated with chronic dieting and weight cycling are not being disclosed to participants and their parents by the Fast Track Trial investigators. In the response to my complaint, Executive Officer, Ms Asra Gholami acknowledged that "The HREC recognises that there is a risk for a young person to develop an eating disorder with exposure to restrictive diets, and in particular very restrictive diets". It must be noted that eating disorder risk is not the only harm associated with this trial. To name but a few of these, further harms identified by people who have signed the petition include the impact of fasting on an adolescent's ability to concentrate and learn in school or participate in physical activity, or the social harms that may arise when an adolescent either does not eat at lunch time or consumes meal replacements at school. There is also an indirect risk that family members and peers of the adolescent, some of whom may have a history of eating disorders, may be impacted by adolescents undertaking these severe dieting regimes.

Parents are not made aware of any risks in the Participant Information Sheet, version 2.1 dated 21st February 2018. Point 7 of the Information Sheet is the only section which refers to possible risks or disadvantages of taking part, and it states:

"We do not expect any side effects or risks associated with this study."

This statement fails to recognise the research evidence provided in my original complaint. Failing to provide sufficient information about the risks of harm associated with a trial is in breach of the general requirements for informed consent as outlined in the National Statement on Ethical Conduct in Human Research 2007 (updated 2018).

Furthermore, parents are not made aware of the availability of any lower risk alternatives to participation in the Participant Information Sheet. In my initial complaint, evidence was provided regarding effective non-diet interventions that focus on helping larger adolescents enhance their long-term physical and mental health. This omission further undermines participants' voluntary decision to participate, as they may believe that calorie-restricted diets are the only option for improving their child's health.

Lastly, and most significantly, this trial does not acknowledge the lived experiences of adults who were put on a weight-loss diets during their childhood or adolescence and subsequently developed life threatening mental illnesses. I urge you to visit the petition and read these comments.

In closing, I would like to reiterate my original concerns about the Fast Track to Health Trial's assumptions, research merit and integrity, and potential to cause harm. Since making my initial complaint I have become aware of additional concerns about: objectivity and transparency of the SCHN HREC, adherence to RACP Paediatric Policy on the Ethics of Research in Children, and informed consent.

I respectfully request a full copy of the minutes of all HREC committee meetings that discussed and approved the Fast Track to Health Trial, including the review of the complaint I submitted. I also request you to disclose either the SOP detailing anonymity of expert review panels, or in the absence of such policies, a list of the panel members involved.

I ask that you urgently review this study, listen to the voices of people with lived experiences, and discontinue the Fast Track to Health Trial in order to protect the long-term physical and mental health of adolescents.

Yours sincerely,

Louise Adams
Clinical Psychologist & Founder,
UNTRAPPED