



Ms Louise Adams
UNTRAPPED

By Email: louise@untrapped.com.au

Dear Ms Adams,

I confirm receipt of your correspondence appealing the decision of the Sydney Children's Hospitals Network Human Research Ethics Committee (SCHN HREC) regarding your complaint about the Fast Track to Health clinical trial. I also acknowledge the concerns raised by yourself and the eating disorder communities in relation to this clinical trial.

As per the SCHN HREC's correspondence in December 2018, the Committee requested for additional safeguards to be put in place to address the safety concerns raised, these have been implemented. The study investigators have also recently met with key community and professional eating disorder organisations and will be continuing these conversations to work through their concerns and modify the trial protocol to ensure that the health and wellbeing of the adolescents in the trial is our highest priority.

I enclose a detailed response to the concerns raised in your correspondence.

Yours sincerely

Dr Michael Brydon
Chief Executive

Date: 27/02/2019

1. Objectivity and transparency of the SCHN HREC

The SCHN HREC is established and operates in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated in 2018) [National Statement]. The SCHN also subscribes to the ethical standards outlined in the Declaration of Helsinki, the Royal Australian College of Physicians Guidelines: Paediatric Policy on the Ethics of Research in Children, and CPMP/ICH Note for Guidance on Good Clinical Practice.

The SCHN HREC has a clear policy for management of conflicts of interests as per the National Statement (Chapter 5.4) which is also reflected in the Committee's Terms of Reference (section 7.3) and Standard Operating Procedures (SOP 027). According to this policy, HREC members are excluded from the meeting where there is a substantial conflict of interest until the HREC has concluded consideration of the matter. If the Chair declares a conflict of interest, the duties of the Chair will fall to the Deputy Chair while the relevant proposal is under discussion.

I confirm that A/Professor Garnett was not involved at all in any considerations, discussions and / or decisions made regarding the initial approval of the Fast Track clinical trial and your complaint. The conflict of interest management policy was strictly adhered to on both occasions.

I note your request for a copy of the SCHN HREC minutes in relation to the Fast Track clinical trial. It is the requirement of the National Statement, paragraph 5.1.37 (t) that HRECs maintain confidentiality of the content of applications and the deliberations of review bodies. In compliance with this requirement and the State Records Act 1998, the SCHN HREC's Standard Operating Procedure (SOP 024) requires that all relevant records of the HREC, including applications, membership, minutes and correspondence, are kept as confidential files. The SCHN HREC's Terms of Reference, section 7.4.1 also states that "the agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially".

We are therefore unable to provide you with copies of the requested HREC minutes. It is important to note however that the SCHN HREC's processes, assessments and deliberations are subject to continuous monitoring by both internal and external authorities to ensure transparency and compliance with ethical and regulatory requirements.

2. Independent Expert Review Panel

I note your request for information regarding the policy for protecting the privacy and confidentiality of external panel members. This can be found within the HREC's Terms of Reference, paragraph 6.1.6 which states "the HREC is free to consult person(s) considered by the HREC to be qualified to advise and assist in reviewing applications provided that there is no conflict of interest and an undertaking of confidentiality is entered into."

A confidentiality agreement is always finalised prior to the engagement of external expert reviewers by the SCHN HREC. The same process was followed for this independent expert advisory panel, and hence the SCHN HREC has a legal obligation to not disclose the reviewers' identity.

As per the previous HREC correspondence, the panel members are not affiliated with the SCHN and do not have any conflicts of interest in providing advice to the SCHN HREC on this matter. The panel members are nationally and internationally recognised for their expertise in the areas of eating disorders and mental health, chronic disease and weight management and research ethics.

The SCHN HREC has followed the aforementioned regulatory and policy requirements in managing conflicts of interest in reviewing your complaint and convening the independent expert advisory panel.

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

This clinical trial was reviewed, approved and funded by the National Health and Medical Research Council (NHMRC). The trial was further assessed by the SCHN HREC and its Scientific Advisory sub-Committee in addition to an independent expert advisory panel following receipt of your complaint. The correspondence from Ms Asra Gholami details the review conducted by the SCHN HREC and the independent expert advisory panel and the justifications for the Committee's final decision. The SCHN as an institution is satisfied that the review process was conducted in compliance with the National Statement and other regulatory requirements with appropriate input from relevant experts.

As per advice from the expert panel, the SCHN HREC requested for additional safeguards to be put in place to strengthen the trial's existing risk management plan. In addition to implementing these additional safeguards, the study team have also consulted with key community and professional eating disorder organisations and are working towards implementing their recommended revisions as well.

The health and mental well-being of those participating in the Fast Track to Health study is the first priority at all times.

4. Informed Consent

As per the SCHN HREC's request, the Participant Information Sheet (PIS) has been updated to disclose the potential risks associated with eating disorders. The previous version of the PIS (V2.4 dated 4th October 2018) had already listed other types of potential risks related to the study interventions. In addition to the PIS documents, participants are also provided with relevant support material regarding the diets, their potential side effects and information on how to manage these side effects.

Please also note that the PIS documents form only a small component of the informed consent process. The National Statement (paragraph 2.2.4) requires that the process of communicating information to participants and seeking their consent should not be merely a matter of satisfying a formal requirement. The aim is mutual understanding between researchers and participants. This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.

The potential participants are offered alternative options during the recruitment and consenting process. The PIS, section 4 (What are the alternatives to participation?) very clearly states that the young people do not have to participate in this clinical trial to receive help. Individuals who decline participation are offered with current standard care or referred to their local GP for care (whichever is their preference).

Moreover, it is the requirement of the National Statement that recruitment is voluntary and non-coercive. The Fast Track clinical trial will only enrol eligible young people who understand the research project and consent to their participation in addition to the consent of their parent / guardian. Participants can withdraw from the trial at any time without providing any reason. This withdrawal will not impact on their relationship with their health care providers and the care they are receiving. All participants are provided with follow up monitoring and support.

The SCHN strongly believes that any weight management program must ensure the psychosocial wellbeing of the participants. This philosophy is the foundation of all relevant programs and research activities.