THE UNIVERSITY OF SYDNEY

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Regulating Autologous Stem Cell Therapies in Australia

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in an Australian Research Council Linkage Project about the therapeutic use of autologous adult stem cells (ASCs) in Australia.

This project combines empirical research (workshops and interviews) and theoretical analysis, with the aim of developing an ethical and socially sustainable regulatory environment for innovation of ASC therapies in Australia.

You have been invited to participate in the **workshop phase** of this study because of:

your interest, as a health consumer, in the issue of ASCs

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the study. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary. So it's up to you whether you wish to take part or not.

By giving consent to take part in this study you are telling us that you:
- ✓ Understand what you have read
- ✓ Agree to take part in the research study as outlined below
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

(2) Who is running the study?

The study is being carried out by the researchers:

- Prof Cameron Stewart, Chief Investigator, University of Sydney
- Dr Tereza Hendl, Postdoctoral Researcher, University of Sydney
- Professor Ian Kerridge, Investigator, University of Sydney
- Professor Catherine Waldby, Investigator, Australian National University
- A/Professor Megan Munsie, Investigator, University of Melbourne
- Dr Wendy Lipworth, Investigator, University of Sydney
- A/Professor Tamra Lysaght, Partner Investigator, National University of Singapore

This study is being funded by the Australian Research Council Linkage Project. Partner Organisations are: The University of Sydney; The University of Melbourne; National University of Singapore; Multiple Sclerosis Research Australia; Arthritis Australia; Motor Neurone Disease Association Of Australia Incorporated/ Motor Neurone Disease Australia Inc.

(3) What will the study involve for me?

During the workshop, you will be invited to discuss ethical and legal issues regarding therapeutic use of autologous ASCs. The workshop will involve 10-20 representatives from health consumer stakeholder groups, such as: Patients, their carers and families. Prior to the workshop you will obtain a short policy brief with an overview of the therapeutic use of autologous ASC therapies in Australia and related ethical and legal challenges. This policy brief will serve as a starting point for discussion in the workshop.

Topics to be explored will include: 1) Are there any challenges caused by the lack of regulation of ASC therapies? If so, what are they? 2) Should any areas of ASC therapies or innovation be exempt from regulation? 3) Should ASC therapies be offered as part of clinical trials and what are the best accessibility criteria?

To encourage free and open discussion, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.

The workshops will not be audio-recorded. Investigators will take notes documenting the discussion for research purposes.

(4) How much of my time will the study take?

The workshop will be conducted at an accessible public venue and will last approximately 3 hours. You will be offered $50 reimbursement for travel to and from the workshop and a $50 supermarket voucher. Refreshments will be provided during the workshop.

(5) Do I have to be in the study? Can I withdraw from the study once I've started?

Participation in this study is completely voluntary. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney and any partner universities and organisations involved in the research project.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by notifying one of investigators above via email, mail or phone.

If you wish to withdraw from the study after the workshop has started or been completed, it will not be possible to identify you to erase your specific contributions. You may also refuse to answer any questions that you do not wish to answer during the workshop.

(6) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect there to be major risks or costs associated with taking part in this study. However, you need to be aware of the following:

Emotional risks

There is a chance that your experience with autologous ASC therapies can stir up memories or issues that be distressing. If you are hesitating now about this, you may wish to discuss this further with Dr Tereza Hendl.

If during the workshop you feel distressed, you are free to take a break or withdraw.

If you feel distressed following the workshop we suggest that you contact your general practitioner for further advice or assistance, or call a support service such as the Mental Health Line (1800 011 511), BeyondBlue (1300 22 4636) or Lifeline (13 11 44) to access counselling.

Disclosure of illegal activity

You need to be aware that if you disclose an engagement in illegal activity of a criminal nature, the researcher may be obliged to notify the authorities. The risk is small and the most likely activity that may come up during a workshop relates to malpractice in medicine.

If you think this may apply to you, you have the choice of (a) declining to participate (b) being aware that during the workshop it is important that you do not reveal any information that may oblige the researcher to inform the authorities. If this inadvertently occurs during the workshop, the workshop will be stopped, while the researcher discusses with you how to proceed with this part of the workshop.

Please note that autologous stem cell therapies are currently unregulated and discussing clinical practice in the realm of ASC therapies does not constitute a disclosure of illegal activity.

(7) Are there any benefits associated with being in the study?

While there are no direct benefits to you of participating in this study, you will have the knowledge that you are making a substantial contribution to the development of an ethical and sustainable regulatory

framework for stem cell therapies and innovation in Australia. Your contribution will be invaluable in informing debates about ethical, clinical and legal aspects of autologous ASCs.

(8) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Any notes taken during the workshop will be de-identified prior to being analysed. Your identity and personal information will only be disclosed with your permission, except as required by law. Study findings may be published, but you will not be identified in these publications.

The de-identified notes will be stored on a secure server and in secure filing cabinets at the Centre for Values, Ethics and the Law in Medicine, University of Sydney. They will be accessible only to the researchers directly involved in this study. Notes will be stored securely for 7 years after the completion of the research, as required by the National Health & Medical Research Council, after which time they will be destroyed.

(9) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(10) What if I would like further information about the study?

When you have read this information, Dr Tereza Hendl and Professor Cameron Stewart will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Tereza Hendl, Postdoctoral Researcher, tereza.hendl@sydney.edu.au, +61 450400230 or Cameron Stewart via the details above.

(11) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one-page summary and/or any articles that have been submitted for publication. You will receive this feedback after the study is finished.

(12) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney 2016/489. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007).* This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:
Telephone: +61 2 9036 9161

- **Email:** ro.humanethics@sydney.edu.au

This information sheet is for you to keep