



PREMSTEM Co-creation Participant Information Sheet

Participant Information

Title	Co-creation activities for the 'The brain injury in the premature born infant: stem cell regeneration research network' (PREMSTEM)
Principal Investigator	Dr Bobbi Fleiss
Co-Investigator(s)	Ms Hannah Tribe Mr Enrique Conches Ms Sella Masselink

What does my participation involve?

1 Introduction

You are invited to take part in this research project, which is called PREMSTEM. You have been invited because you have submitted an Expression of Interest (EOI) to take part in the project's co-creation activities and have self-identified as being able to participate as a representative of a named stakeholder group. Your contact details were obtained from the EOI that you submitted on Eventbrite.

This Participant Information Sheet tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative or friend.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the *PREMSTEM co-creation consent form*. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project's co-creation activities

In addition, you'll be invited to sign the *PREMSTEM co-creation release and data form* which details how we might share still images from the workshops on social media accounts – signing this form is not compulsory.

We recommend that you keep a copy of this Participant Information Sheet and the consent form for your records.

2 What is the purpose of this research?

Aim of the project and its significance

PREMSTEM is a research project seeks to create a new therapy to treat brain damage associated with preterm birth using stem cells donated from umbilical cord tissue. The aim of the therapy is to improve the quality of life for infants with brain injury and reduce the societal costs of their special needs.

How the project is intended to fill any gap in knowledge

PREMSTEM aims to take its stem cell therapy to clinical trial. Through co-creation activities, the project team aims to identify potential issues and concerns related to the acceptance and rollout of the stem cell therapy to the clinic, according to the various stakeholders within the neonatal ecosystem.

People outside the research team have different personal and professional experiences and circumstances. Their participation and contributions will help us to identify and plan for future challenges in taking our research from the lab to the clinic.

How it may contribute to research in the future

The co-creation activities aim to increase knowledge and understanding to improve social welfare and individual wellbeing in the space of healthcare options for preterm-born infants. The activities will use methods that are well established, will be intended to be as unobtrusive as possible to achieve its aims, and will be undertaken by experienced and highly trained facilitators.

The inputs and insights revealed in the co-creation workshops, interviews and surveys will help to refine PREMSTEM communications to the general population. They will also help the research team to develop an exploitation strategy which outlines the best way for the researchers to take the stem cell therapy to future clinical trials, by incorporating the views of people who represent the eventual end users of the treatment.

This research has been funded by the European Union's Horizon 2020 Research and Innovation program under Grant Agreement No 874721.

The co-creation activities are being coordinated by [RMIT Europe](#).

Experts from [Punk Design](#) will facilitate the co-creation activities (workshops, interviews, surveys) and provide analysis and reporting to PREMSTEM. Enrique Conches has more than 20 years of expertise in technology, mainly as project leader and IT lead (local and international projects). He's a specialist in design thinking and LEGO® SERIOUS PLAY®. Sella Masselink, a specialist in design thinking, is a design sprint trainer and facilitator with experience in designing new methodologies that help solve current global challenges. She has master's degrees in gamification and neuropsychology.

3 What does participation in this research involve?

Prior to commencing the co-creation activities, each participant will be required to sign the *PREMSTEM co-creation consent form*. Each participant will also be invited to sign the *PREMSTEM co-creation release and data form* – signing this form is not compulsory. The consent form can be either digitally signed or printed, signed and scanned and returned to info@premstem.eu.

Individuals who submitted EOIs will be invited to participate in a volunteer capacity in PREMSTEM's co-creation workshops. Around 20-25 participants will be required per session, and we will aim for consistency among the groups. If an individual cannot attend a session, another person who submitted an EOI who represents the same stakeholder group will be invited to attend. In addition, a small number of people who submitted an EOI will be invited to

participate in a one-on-one interview, conducted in English with an expert from Punk Design to reveal deeper insights during the co-creation process.

Ten co-creation workshops will take place during the period May 2022 to June 2023, approximately on a monthly basis.

If invited to attend, participants will be encouraged to attend as many workshops as possible. Participants can notify the research team at any time if they no longer wish to be invited to participate in the PREMSTEM co-creation activities.

Video or audio recordings of co-creation activities (including workshops and interviews) are for the sole use of Punk Design and PREMSTEM. The *PREMSTEM co-creation consent form* asks for participant consent to use such recordings to create internal recommendations and in PREMSTEM reporting and deliverables.

Participants will be invited to sign the *PREMSTEM co-creation release and data form* to give their consent for static screenshot images from co-creation workshops to be used as promotional materials on the website and social media accounts of PREMSTEM and RMIT Europe.

To protect participant identities, participants will be asked to give themselves an alias (alternative name) as part of the EOI process. They will use their alias when they participate in co-creation activities.

The co-creation activities will take place in the English language. Interpreters will not be available during these activities.

All activities will take place through online channels.

There are no costs associated with participating in this research project, nor will participants be paid.

4 Other relevant information about the research project

9 participant stakeholder groups are involved in this research project.

People participating in the co-creation activities will have self-identified as a representative of one of the following through the EOI process:

- Member of PREMSTEM Patient/Consumer Advisory Board or patient/consumer organisation/advocacy group
- Member of PREMSTEM Ethics/Institutional Review Board committee
- Parent/carer of a preterm baby or young child who might be eligible for a future stem cell treatment and/or adult who was born preterm
- Parent/carer of a child with no known health issues
- Clinician or other health professional
- Researcher (preferably in the health sciences)
- Policy maker
- Member of a governance/regulatory body
- Other interested party

The co-creation activities are part of the wider PREMSTEM project whose full team is listed on the [partners page](#) of the website. Co-creation is being coordinated by RMIT Europe and facilitated by Punk Design.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part in the PREMSTEM co-creation activities, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the researchers or with RMIT University.

Interviews

If you take part in a one-on-one interview, you may stop the interview at any time. Unless you say that you want us to keep them, any recordings will be erased and information you have provided will not be included in the study results. You may also refuse to answer any questions that you do not wish to answer during the interview.

Workshops

If you take part in a workshop, you are free to stop participating at any stage or refuse to answer any questions.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, you may appreciate contributing to knowledge as someone with an interest in the area of stem cell research and its potential to treat brain injury in the preterm population.

Your participation in the PREMSTEM project co-creation activities will help to generate internal recommendations to refine and adjust the communication and exploitation strategies of the project.

7 What are the risks and disadvantages of taking part?

Psychological distress

Depending on your personal experiences, in the setting of discussing the issues related to preterm birth and the outcomes for babies you may feel that some of the questions we ask bring up uncomfortable feeling and memories. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed because of your participation in the research project, members of the research team will be able to discuss appropriate support for you. Neither Punk Design nor PREMSTEM will intentionally collect sensitive personal data such as medical history data from co-creation participants.

Workshop discussions

Participants in the sessions will also be asked to maintain privacy and confidentiality. However, please keep in mind that it is advisable that you do not reveal anything too personal.

Online surveys

This project will use an external website to create, collect and analyse data collected in a survey format, for example to receive feedback on the workshop sessions. RMIT Europe uses Typeform to run online surveys. If you agree to participate in this survey, the responses you provide will be exported to the RMIT Europe SharePoint site and shared with Punk Design for analysis and continuous improvement of the activities. No personal information will be collected in the survey so none will be stored as data.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify the PREMSTEM team (info@premstem.eu). There are no negative consequences or implications of withdrawing from this study at any time.

You have the right to have any unprocessed data withdrawn and destroyed, providing it can be reliably identified and will not require the destruction of group session data.

9 What happens when the research project ends?

As per the grant agreement, PREMSTEM is obligated to submit deliverables (information gained during the project) to the European Commission. There is one deliverable linked to the co-creation activities that will lead to the creation of a publicly available document.

This document, *The Open Innovation activities: Co-Creation Sessions report* (deliverable D6.3 led by RMIT Europe), will reflect on the process, activities, and outcomes of the project's co-creation programme. Any reference to insights and inputs revealed in co-creation activities will be attached to the broad stakeholder groups and not to any individual participants to protect participant anonymity. This public deliverable will be submitted to the European Commission and be made available on the PREMSTEM website. It may also be referenced in PREMSTEM promotional communications (e.g., on social media). We will also share this report with everyone who took part in, and contributed to, the co-creation activities.

Inputs and insights contributed by participants in co-creation activities will also help to refine two **confidential** project deliverables: the *Communication and dissemination plan* (deliverable D6.1 led by EFCNI) and *Exploitation Plan* (deliverable 6.4 led by [Chiesi](#) who is the pharmaceutical company supplying the project's stem cells). These reports are limited in dissemination, readership, and usage to the members of the PREMSTEM consortium and European Commission and insights from the co-creation sessions will also be attributed to the broad stakeholder groups and not to any individual participants to protect participant anonymity. The purpose of these two deliverables is to support the development of a stem cell product that can be used in a clinical setting to repair brain damage caused by preterm birth.

How is the research project being conducted?

10 What will happen to information about me?

Personal information collected during the EOI process (e.g., name, email address) will be collected via RMIT Europe's Eventbrite account. This data will be exported by RMIT Europe to the RMIT Europe server and stored securely in a dedicated folder on SharePoint. To protect personal identities, individuals will be asked to choose an alias (alternative name) during the EOI process for them to use during the co-creation activities.

A copy of the EOI information, which removes individuals' names and email addresses, will then be shared with Punk Design and relevant PREMSTEM partners to identify who to invite to take part in the co-creation activities. Besides ensuring a representation from all stakeholder groups, this screening process will prioritise individuals who have indicated the most availability as we aim for consistency among the participants attending the sessions.

Workshops will be organised using Zoom. RMIT Europe will be responsible for liaising with participants and inviting them to attend. Participants will be asked to use their alias (alternative name) when entering the sessions in order to protect identities.

The feedback from co-creation sessions will be aggregated and analysed in relation to stakeholder groups rather than individuals. Data collected will be aggregated before analysis.

Any video or audio recordings of co-creation activities (including workshops and interviews) are for the sole use of Punk Design and PREMSTEM and will be stored securely on the RMIT Europe SharePoint. If transcribed, any identifying information will be removed during the transcription process or changed if short anecdotal information is deemed to add value to the analysis. RMIT Europe is responsible for making recordings of co-creation activities using Zoom

and will keep all related files on its SharePoint with a backup service. These recordings will be shared with a limited number of people from Punk Design in order for them to carry out their brief and report back to PREMSTEM.

PREMSTEM partners are responsible for the storage of the data they produce and/or collect. To keep the data safe and secure, local computers and/or servers at partner's institutions will be used. Access to the computers and servers are restricted to the participants of the PREMSTEM project. While collecting, processing, and analysing data (dynamic phase), regular back-ups will be implemented regularly to avoid accidental or malicious data loss.

Neither Punk Design nor PREMSTEM will intentionally collect sensitive personal data such as medical history data from co-creation participants. That said, it cannot be excluded that sensitive personal data will be inadvertently collected, for instance during audio or video recordings of workshops or interviews. In case sensitive personal data is unintentionally collected, appropriate measures are in place to safeguard the data including limited access and anonymisation before analysis.

Punk Design and PREMSTEM will take steps to ensure that these data are not further processed or shared in line with RMIT's data protection policies. RMIT staff involved in the co-creation activities have completed the RMIT data management online training course (Data@RMIT).

By signing the consent form, you consent to the research team collecting and using information from you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential as outlined above.

The results of the co-creation activities will be published and/or presented in a variety of forums including *The Open Innovation activities: Co-Creation Sessions report*. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Any reference to insights and inputs revealed in co-creation activities will be attached to the broad stakeholder groups rather than individual participants to protect participant anonymity. This report will be published on the PREMSTEM website and may be referenced in PREMSTEM communications to promote the project (e.g., on social media).

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information that you provide can be disclosed only if (1) it is protect you or others from harm, (2) if specifically allowed by law, (3) you provide the researchers with written permission. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored.

Once we have completed our data collection and analysis, the data will remain on the RMIT Europe server where it will be stored securely for five years. The data on the host server will then be deleted and expunged.

11 Who is organising and funding the research?

The PREMSTEM co-creation activities are being conducted by Punk Design in consultation with the PREMSTEM team. They are coordinated by RMIT Europe.

12 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This research project has been approved by the RMIT University HREC.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

13 Further information and who to contact

If you want any further information concerning this project, you can contact the following people:

Researcher contact (RMIT University)

Name	Dr Bobbi Fleiss
Position	Principal investigator
Email	bobbi.fleiss@rmit.edu.au

Coordinator contact (RMIT Europe)

Name	Ms Hannah Tribe
Position	Co-investigator
Email	hannah.tribe@rmit.edu.au

Facilitator contact (Punk Design)

Name	Mr Enrique Conches and Ms Sella Masselink
Position	Co-investigators
Email	econches@punkdesign.barcelona and sellamasselink@gmail.com

14 Complaints

Should you have any concerns or questions about this research project, which you do not wish to discuss with the researchers listed in this document, then you may contact:

Reviewing HREC name	RMIT University
HREC Secretary	Vivienne Moyle
Telephone	+61 3 9925 5037
Email	humanethics@rmit.edu.au
Mailing address	Manager, Research Governance and Ethics RMIT University GPO Box 2476 MELBOURNE VIC 3001 Australia