

Perry Cross Spinal Research Foundation

# The Spinal Injury Project

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Cell Transplantation and Rehabilitation Human Clinical Trial

Partnership Prospectus

In partnership with



# What if the ability to repair a spinal cord injury became a reality in the next five years?

The Spinal Injury Project at Griffith University, in partnership with the Perry Cross Spinal Research Foundation, is on the cusp of making this happen with a world-first Cell Transplantation and Rehabilitation Human Clinical Trial.

The project team is a leading group of research specialists including bioengineers, medical doctors, biological scientists and educators working together to develop this breakthrough treatment.

The research was first initiated by the late Griffith University Professor Emeritus, and 2017 Australian of the Year, Alan Mackay-Sim almost 20 years ago. He was a pioneer in stem cell research and was successful in taking cells from the olfactory (nasal) system, transplanting them to the injury site and demonstrating that it was safe for use in humans.

Building on Professor Mackay-Sim's incredible legacy, our ongoing research has demonstrated that repair of a spinal cord injury is possible, and the clinical trial will show that repair can be a reality.

Together with generous donors and our key partners the Motor Accident Insurance Commission Queensland (MAIC) and the Clem Jones Foundation in Brisbane, we have provided significant investment, leadership and advocacy to reach this crucial stage.

**The late Emeritus Professor** Alan Mackay-Sim AM

We are now seeking bold and committed philanthropic partners to join us to ensure that the clinical trial can commence in 2024.

We invite you to join us today on this urgent and vital transformational journey of discovery to recovery for the tens of thousands of people in Australia and the millions across the world, who every day live their lives with the challenges of a spinal cord injury.

Prof James St. John Head Centre for Neurobiology and Stem Cell Research Griffith University





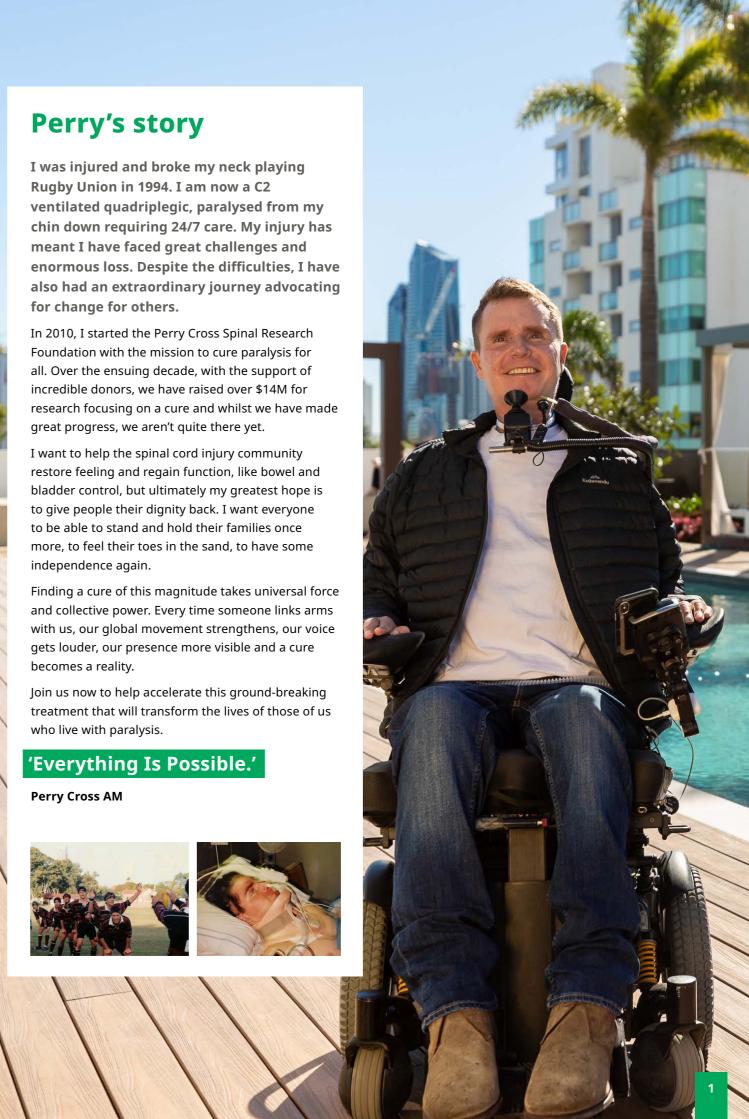


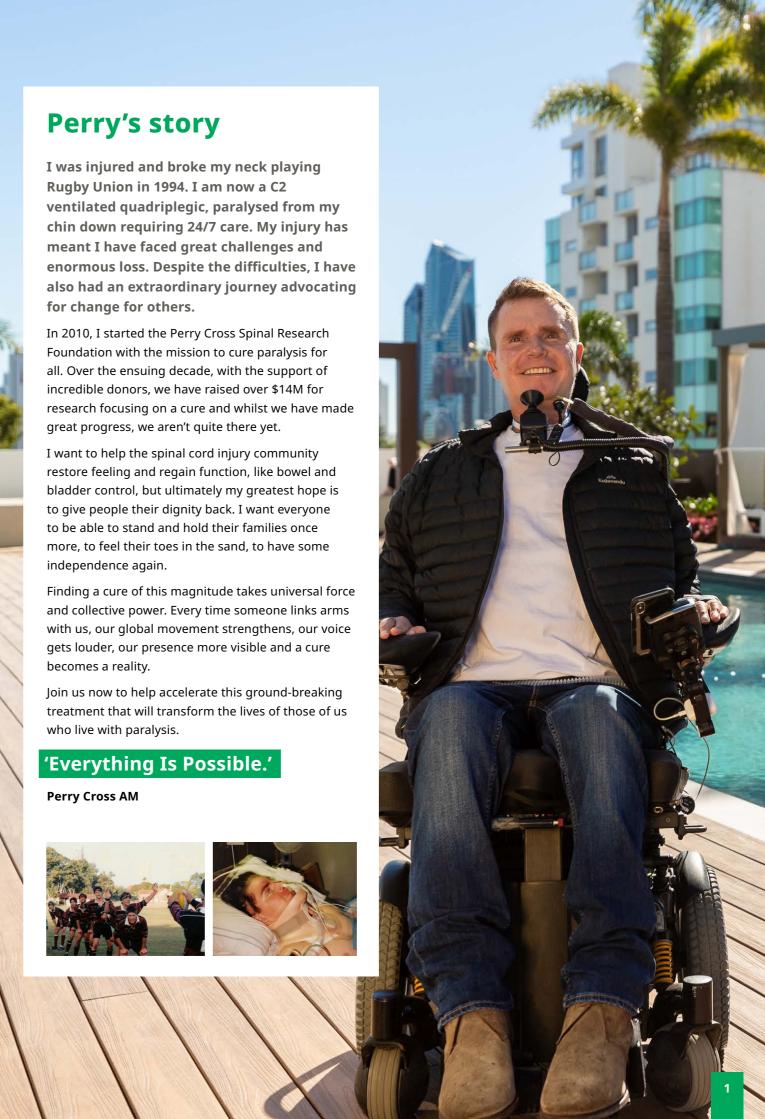
Perry Cross AM

Founder & President

Perry Cross Spinal Research Foundation

CLEM JONES CENTRE FOR NEUROBIOLOGY AND STEM CELL RESEARCH







## Lindsay's story

Brisbane local Lindsay Nott is a man who has made the most out of life.

On the last day of year 12 Lindsay went to South Bank Parklands in Brisbane to celebrate. "Four of us ran into the pool, three came up and I was the unlucky one that hit my head and the rest is history."

Lindsay became a C4/C5 quadriplegic because of his accident and endured many painful months in the spinal unit, devastated.

With the support of his family and friends, Lindsay has gone on to live in his own home, travel the world and find fulfilling employment.

"There is light at the end of the tunnel, we are getting there. The rehabilitation work being done at Making Strides in conjunction with the research in the lab at Griffith University is amazing. We are on the cusp of a cure for paralysis."

## What is spinal cord injury?

The term 'spinal cord injury' refers to damage to the spinal cord resulting from trauma, disease or degeneration.

Symptoms may include partial or complete loss of sensory function or motor control of arms, leqs and/or body (paralysis). The most severe injury affects bowel or bladder control, breathing, heart rate and blood pressure.

Spinal cord injury can happen to anyone at any time and the recovery of function varies greatly with the most severe cases showing minimal to no recovery.



20,800 Australians have spinal cord injuries & there are 400 new traumatic injuries every year

Males account for 70% of spinal cord injuries





58% of spinal cord injuries resulted in paraplegia



The main cause for injuries







of spinal cord injuries resulted in quadriplegia



# The Discovery toRecovery Journey:2002 to 2023

## 2014

#### A human trial by Polish and British researchers demonstrated that restoration of function is possible.

Within 6-12 months after transplantation a patient, who had been paralysed for several years prior to the treatment, regained some motor function of his legs, bladder control, and most importantly, sensation.

# 2021

Intensive rehabilitation trials begin to test the delivery and safety of providing long-term intensive rehabilitation to people living with spinal cord injury.

These trials have demonstrated that intensive long-term rehabilitation is safe and suitable for people living with chronic spinal cord injury.

## 2002

Ground-breaking human clinical trial led by the late Alan Mackay-Sim, 2017 Australian of the Year and Griffith University Professor Emeritus.

This trial was successful in demonstrating that taking cells from the olfactory (nasal) system and transplanting them to the injury site is safe for use in humans.

## 2017

A world-first, innovative 3D nerve bridge was developed and the pre-clinical research successfully demonstrated the safety of the treatment.

At the same time, the Queensland Government through the Motor Accident Insurance Commission, awarded Griffith University \$16 million over 9 years for pre-clinical research to develop a therapy using olfactory cell transplantation.



#### Commencement of Cell Transplantation and Rehabilitation Human Clinical Trial.

This trial will test the safety and efficacy of the cell transplantation and rehabilitation in 10 people living with spinal cord injury and will take 2 years.

## **Steve's Story**

After a camping trip in Port Macquarie, Steve's life changed forever.

"I was away for the weekend camping with mates and I jumped into a pool. There was a large step that jutted out and I just didn't see it. I bumped my head on the step, unfortunately."

Steve lay face down in the pool, unable to breathe and as a result of this tragic accident, he was injured at C4/C5 and was left a quadriplegic.

Steve has worked hard on his outlook and approach to life. He has focused on his rehabilitation and now lives independently and has been able to return to work.

"We need a cure for paralysis. There is so much complexity, angst and heartbreak for people with injuries."



"Despite the challenges, I try to stay positive. I know there's more to life than just this. I am optimistic about a cure for paralysis." "I've had the privilege of visiting the lab and seeing the amazing work Griffith is doing. The success they have already had is incredible. It's not a fantasy, a cure is a reality."



## **Kurt's story**

Kurt Drysdale was injured just before his 21st birthday playing rugby league. He is paralysed from the neck down and needs a respirator to breathe.

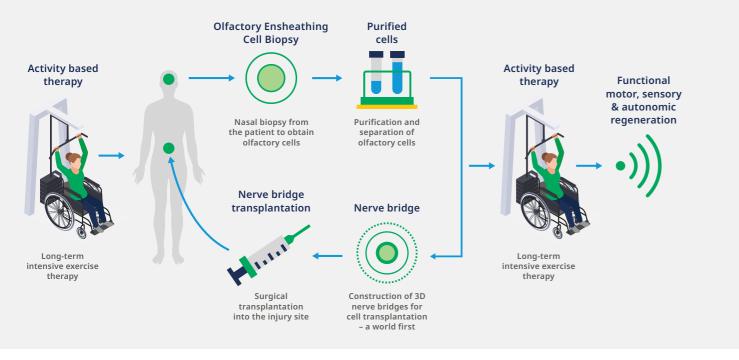
"It was tough both mentally and physically. Obviously, I couldn't feel or move, but then watching my family and friends go through the shock of seeing me this way was also extremely difficult."

Kurt has had to learn to swallow and talk again and he needs full time support to do everyday tasks. He is working hard on his rehabilitation and is determined to see some recovery.

## The treatment

This ground-breaking, world-first treatment involves the transplantation of the patient's own olfactory cells from the nose into the spinal cord. Central to the success of this treatment is intensive rehabilitation that takes place before and after the cell transplantation.

Having proven that the treatment is effective in preclinical research, the team is now ready to test the therapy in a human clinical trial with an anticipated start in 2024. The trial will have 10 participants, will take 2 years and will test the safety and efficacy of the cell transplantation and rehabilitation.



#### **Intensive Rehabilitation**

The clinical trial will require participants to take part in an intensive rehabilitation program before and after the cell transplantation.

Participants will train intensively at the gym for 16 weeks. Throughout the trial functional, medical and psychological assessments will be conducted to determine participants outcomes.



#### **World-First Nerve Bridges**

The Spinal Injury Project is reinventing and rethinking how cells can grow leading to the creation of new cell products. By combining advanced cell purification and engineering techniques the team has designed threedimensional nerve bridges that allow neurosurgeons to precisely place the cells into the injury site. This dramatically improves the survival of the cells.

By enabling the cells to form stable connections within the nerve bridge prior to transplantation, the cells rapidly form a permissive bridge over the injury site that allows the spinal cord nerve cells to regenerate. Using the patient's own cells greatly improves the safety of the treatment. This results in a treatment that has extremely rapid production times, is more effective and more affordable.

## **The Spinal Injury Project Team** making medical history

The Spinal Injury Project is part of the Clem Jones Centre for Neurobiology and Stem Cell Research and is directed by Professor James St John and Associate Professor Jenny Ekberg. Together they lead a team of internationally recognised researchers based in state-of-the-art laboratories at the Menzies Health Institute Queensland and the the Griffith Institute for Drug Discovery.

The team has an impressive track record and have won two major awards: the National Health and Medical Research Council Marshall and Warren Innovation Award 2019; and the Research Australia Discovery Award 2020-2021.





Prof James St John Head of the Clem Jones Centre for Neurobiology and Stem Cell Research and project leader.

**Associate Prof** Jenny Ekberg Associate Prof of Neurophysiology at Menzies Health Institute

Qld and project leader.



Dr Ronak Reshamwala Senior Research Fellow. Ronak is a medically trained doctor and worldrenowned spinal surgeon.



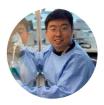
**Ms Genny Kroll-Rosen** and Mr Jim Barrett The associate investigators from Making Strides, the specialist rehabilitation service provider for the trial.

Dr Mariyam Murtaza Senior Research Fellow. Mariyam's expertise is in human cell production.



**Prof Dianne Shanley** Clinical psychologist. Dianne will conduct and analyse the psychosocial assessments during the trial.

The treatment has also been co-designed with the spinal cord injury community to ensure that it meets their expectations and needs. The Spinal Cord Injury National Consumer Research Panel consisting of ten people from around Australia living with spinal cord injury regularly advises the team about the research direction and provides input into the therapy design.



Dr Mo Chen Senior Research Fellow, Mo is a bioengineer and the inventor of the nerve bridge production technology.



Dr Ali Delbaz Research Fellow. Ali is an expert in molecular and cellular biology.



**Dr Andrew Rayfield** Senior Research Fellow Andrew is an expert in translational research and commercialisation.



**Ms Charmion** Grant-Thompson Physiotherapist and Research Fellow. Charmi oversees the rehabilitation and clinical trial components.



**Dr Brent McMonagle** PCSRF Scientific Director. Brent is a leading ENT surgeon and one of the clinical leads for the project.



**Ms Yasmin Arena-Foster** Research Assistant. Yasmin specialises in research translation and clinical trial planning.

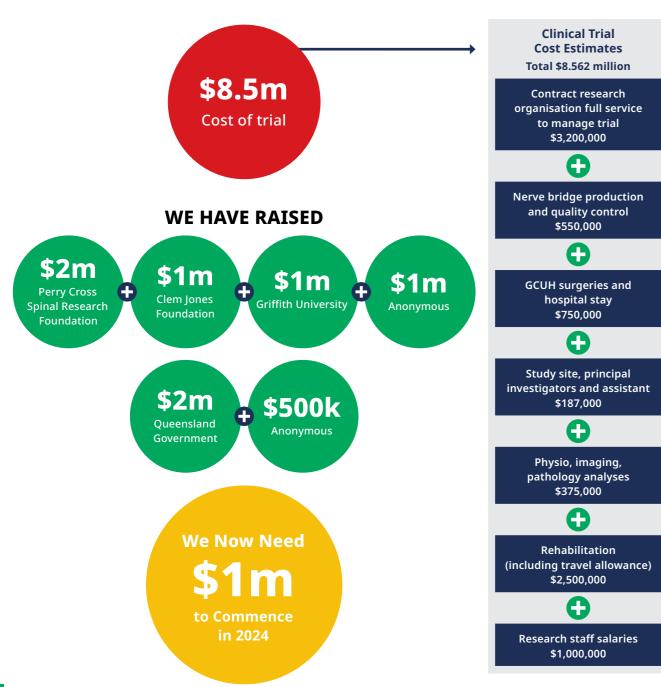
## **Investment required**

Together with our key partners over \$20 million has already been invested to get to this exciting stage. We now require further investment of \$8.5m to commence the clinical trial and to safeguard the continuity and success of the research.

The economic cost of spinal cord injury to the Australian economy has been quantified at a staggering \$3.7 billion per annum and a lifetime cost of \$74 billion for the 20,800 Australians with spinal cord injury. These costs are attributed to personal and health care, lost productivity and reduced wellbeing for patients, families and friends.

The \$8.5m investment required is a small percentage when compared to the ongoing economic costs of spinal cord injury. Without an effective treatment for spinal cord injury, the emotional and financial costs to individuals, their families and to our community are devastating and life-long.

The Spinal Injury Project team is now ready to commence the trial in 2024, subject to the full investment target being confirmed.



## This is our moment to make history and we need your help

The Cell Transplantation and Rehabilitation Human Clinical Trial is a truly inspirational endeavour. Through generous supporters like you, our funding partners, philanthropists, and our incredible fundraising community, we are already well on the way to reaching our \$8.5m target. We now need further investment to ensure the trial can commence in 2024.

You have the opportunity to play a part in medical history. This research will improve the quality of life for people suffering with paralysis and the success of this human clinical trial will result in a world-first treatment for thousands of Australians and millions of people across the world.

We are now urgently seeking philanthropic partners to support this ground-breaking trial.

We need the support of like-minded people who are inspired by the potential for this research, and we invite you to reach out and join us on this journey of discovery to recovery.

## We value all contributions and would love to discuss how you can make an impact.

### To find out more and to book a lab tour, please contact:

Mrs Jen Hutchings Philanthropy Manager Perry Cross Spinal Research Foundation

0406 123 640 ien@pcsrf.org.au

www.pcsrf.org.au

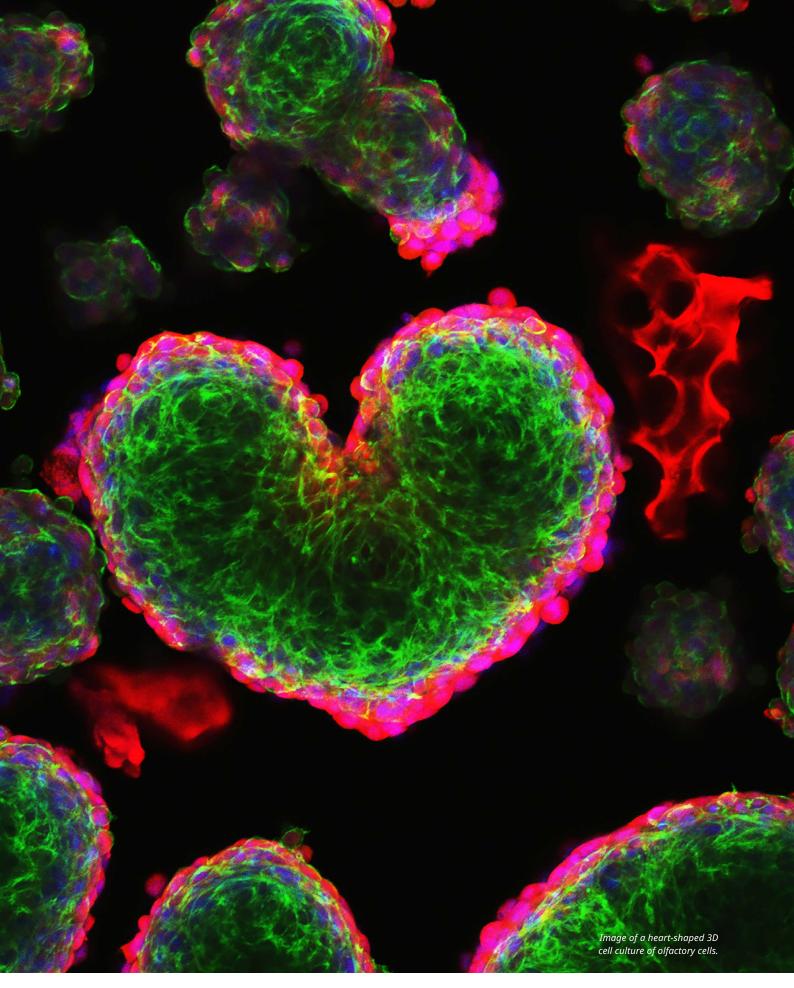
















Perry Cross Spinal Research Foundation *To Cure Paralysis For All* \*\*

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