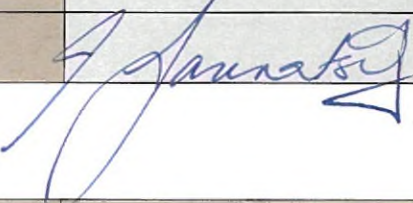


# Documentation of Investigational Site Qualifications, Adequacy of Resources and Training Records

## Standard Operating Procedure

### Western Health

<b>SOP reference</b>	001
<b>Version</b>	3.0 dated June 2019
<b>Effective Date</b>	June 2019
<b>Next Review Date</b>	June 2024
<b>Approved/Endorsed by:</b>	Mr Bill Karanatsios, Research Program Director
<b>Signature and date</b>	 23/12/2021

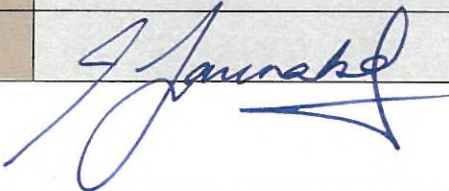
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated and aligned with MACH SOPs

# Trial Master File and Essential Documents

## Standard Operating Procedure

### Western Health

SOP reference	002
Version:	3.0 dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	 23/12/2021

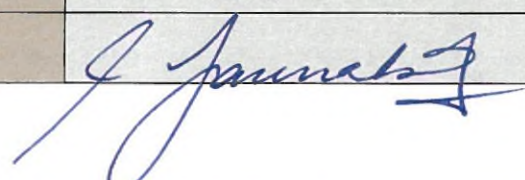
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

# Communication with HREC, Trial Sponsor and Insurer

## Standard Operating Procedure

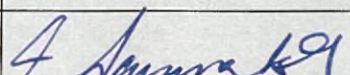
### Western Health

<b>SOP reference</b>	003
<b>Version:</b>	3.0 June 2019
<b>Effective Date</b>	June 2019
<b>Next Review Date</b>	June 2024
<b>Approved by</b>	Mr Bill Karanatsios, Research Program Director
<b>Signature and date</b>	 2.3/12/2021

**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

# Protocol and Investigational Brochure Content, Design, Amendments and Compliance Standard Operating Procedure Western Health

SOP reference	004
Version:	3.0 Dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	 23/12/2021

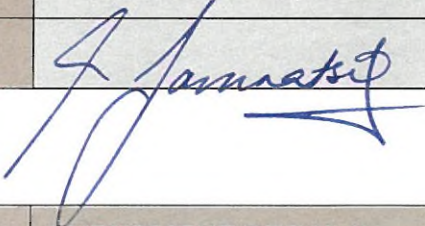
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

# Receipt and Handling of Investigational Product

## Standard Operating Procedure

### Western Health

<b>SOP reference</b>	005
<b>Version:</b>	3.0 dated June 2019
<b>Effective Date</b>	June 2019
<b>Next Review Date</b>	June 2024
<b>Approved by</b>	Mr Bill Karanatsios, Research Program Director
<b>Signature and date</b>	 23/12/2021

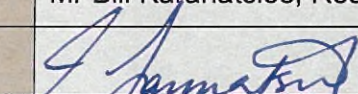
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

# Informed Consent Procedures and Writing Informed Consent Forms

## Standard Operating Procedure

### Western Health

<b>SOP reference</b>	006
<b>Version:</b>	4.0 dated September 2021
<b>Effective Date</b>	September 2021
<b>Next Review Date</b>	June 2024
<b>Approved by</b>	Mr Bill Karanatsios, Research Program Director
<b>Signature and date</b>	 28/12/2021

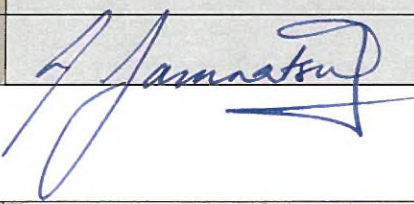
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs & Medical Treatment Planning and Decisions Act (2016)
4.0	September 2021	Updated to include video telehealth as a form of remote consent/re-consent

# Case Report Forms Source Documents Record Keeping and Archiving

Standard Operating Procedure

Western Health

SOP reference	007
Version:	3.0 dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	 28/12/2021

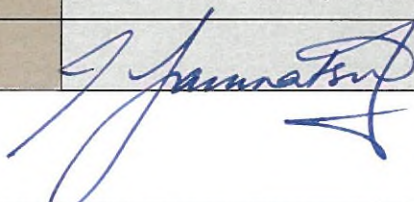
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs, WH EMR and corporate records requirements

# Site Initiation and Closeout

## Standard Operating Procedure

### Western Health

SOP reference	008
Version:	3.0 dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	 28/12/2021

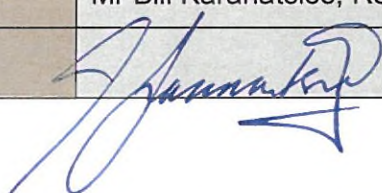
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs



# TGA NOTIFICATION AND SAFETY REPORTING

## Standard Operating Procedure Western Health

SOP reference	009
Version:	3.0 dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	 28/12/2021

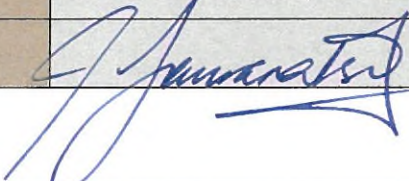
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs, TGA Australian Clinical Trial Handbook (v2.2 October 2018) and NHMRC Guidance on Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)

# INVESTIGATOR RESPONSIBILITIES

## Standard Operating Procedure

### Western Health

SOP reference	010
Version:	3.0 dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	 28/11/2019

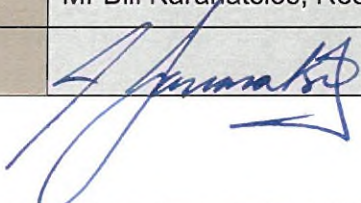
#### Amendment History

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

# Sponsor Obligations for Investigator Initiated Trials

## Standard Operating Procedure

### Western Health

SOP reference	011
Version:	3.0 dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	 28/12/2020

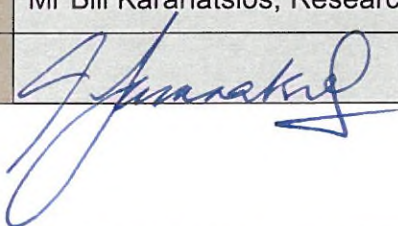
**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

# HANDLING AND SHIPPING OF INFECTIOUS SUBSTANCES FOR CLINICAL TRIALS

## Standard Operating Procedure

### Western Health

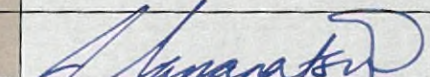
SOP reference	012
Version:	3.0 dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	 28/12/2021

#### Amendment History

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

# Standard Operation Procedure (SOP) Creation, Implementation and Revision

## Standard Operating Procedure Western Health

SOP reference	013
Version:	3.0 dated June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Project Director
Signature and date	 28/12/2021

**Amendment History**

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs