

The unblinding or code breaking procedure will be followed in the event of a medical emergency where knowledge of the blinded treatment is necessary such as an adverse event, overdosing of trial treatment, Suspected Unexpected Serious Adverse Reaction (SUSAR) or if requested by the Safety Monitoring Committee (SMC).

Abbreviation and nomenclature:

TUT: Trial Unblinding Team. At least two personnel from the data management team

PI: Principal Investigator.

Delegate: The PI may delegate a clinically-trained member of the Steering Group to undertake PI tasks specified in this SOP in the event that the PI is not available.

CRF: Case Report Form

SGM: Steering Group Meeting

SMC: Safety Monitoring Committee

Note to file: An electronic or paper document necessary to record any exchanges during the unblinding process.

Section A: Unblinding procedure

Please see **Appendix A** for contact information and **Appendix B** for unblinding process workflow.

1. The request to unblind a trial treatment is received from a parent/GP/responsible clinician/the Chair of the Safety Monitoring Committee (SMC):
 - verbally, by phone or in person (hPOD Study phone: 0800 00 4763, Study Coordinator, or Principal Investigator (PI) cellphone), or
 - by email (hPOD@auckland.ac.nz, Study Coordinator or directly to PI/Delegate).
2. Team member in receipt of the request (if not PI/Delegate) contacts the PI/Delegate to advise. Email correspondence received from the requestor should be forwarded to the contacted PI/Delegate for their information.

Please note: Should the PI or Delegate be directly involved in the clinical care of the participant, the request to unblind must be directed to another Delegate.
3. PI/Delegate considers the request and if necessary, contacts the requester to discuss unblinding options. The PI/Delegate will normally discuss the request with another member of the Steering Group before arriving at a decision.

4. If it is agreed that unblinding is not necessary, the PI/Delegate advises the requester and complete a 'note to file' documenting the exchange.
5. If the PI/Delegate agrees unblinding is appropriate, unblinding will proceed (see **Section B**)
6. Once unblinding has occurred (and if PI has not obtained this information directly from the website), the outcome will be provided to the PI/Delegate by the Trial Unblinding Team (TUT) or Study Statistician. The PI/Delegate will then advise the requestor.
7. The TUT will ensure that a copy of the 'note to file' or email request and/or decision is attached to the relevant CRF, and that the event is recorded in the database and data management systems within 7 days.
For audit purposes the time of interactions will be logged on the 'note to file' or in the case of email transactions the message headers preserved.
8. The TUT will ensure that the unblinded property of the study participant is set to 'yes' in the database.
9. The TUT will inform the Study Coordinator of the request for unblinding, and whether unblinding occurred (but not the outcome of unblinding). The Study Coordinator will report this to the Trial Steering Group at the next Steering Group Meeting.

Section B: Unblinding methods

Three unblinding methods are available.

1. Secure online webpage with password.

The PI can either directly access the webpage, or request that this be performed by the TUT.

1. **Access Webpage Link:** URL: <https://www.liggintrials.org/hPODM/>
2. **Requirements:** Password, Study ID/Trial treatment Pack number, Name of PI/Delegate requesting unblinding, name of TUT member undertaking unblinding (if not the PI).
3. **Notification:** Email notification will be sent to the TUT and the PI/Delegate involved in the process after successful unblinding.

2. Password protected excel file (TUT)

1. **Access TUT:** Email/SMS/Phone call from the PI/Delegate to TUT
2. **Requirements:** Password, Study ID/Trial treatment Pack number, Name of PI/Delegate requesting unblinding, name of TUT member undertaking unblinding.

3. **Action:** TUT opens password protected excel file and determines treatment allocation.
4. **Notification:** Email notification will be sent to the TUT and to the PI/Delegate involved in the process after successful unblinding.

3. Trial Statistician

Trial Statistician can be requested to unblind if the above unblinding methods are not successful.

1. **Access TUT:** Email/SMS/Phone call from the PI to trial statistician
2. **Requirements:** Password, Study ID/Trial treatment Pack number, Name of PI/Delegate requesting unblinding, Name of study statistician undertaking unblinding.
3. **Action:** Study statistician opens password protected excel file and determines treatment allocation.
4. **Notification:** Email notification will be sent to the TUT and to the PI/Delegate involved in the process after successful unblinding.

Appendix A

PI and Delegates

Name	Email	Contact
Professor Jane Harding		
Dr. Jane Alsweler		
Professor Caroline Crowther		

hPOD Trial Steering Group

Name	Email	Contact
Professor Jane Harding		
Professor Caroline Crowther		
Dr. Jane Alsweler		
Dr. Joanne Hegarty		
Dr. Richard Edlin		
Mr. Greg Gamble		

Trial Unblinding Team (TUT) and Study Statistician

Name	Email	Contact
Khan Safayet Hossin (TUT)	s.hossin@auckland.ac.nz Safayet.hossin@gmail.com	0221885920
Karen Frost (TUT)	k.frost@auckland.ac.nz	
Greg Gamble (TUT, Study Statistician)	gd.gamble@auckland.ac.nz	

Other Contacts

Name	email	Contact
Kelly Fredell (Study Coordinator)	k.fredell@auckland.ac.nz	

Appendix B

Unblinding process workflow

