INVESTIGATOR PROGRESS REPORT

010-FORM-HREC

Please forward to RANZCO HREC twelve months from date of approval, and annually thereafter unless requested more frequently in the HREC specific conditions for the study.

Protocol title:			
Principal Investigator:			
RANZCO HREC reference number:		Protocol version:	
Date of study approval: _ _/_ _/_ _		Date of report: _ _/_ _/_ _	
If the study is inactive, terminated or never started, please state reasons:			
Study Summary			
Results obtained to date, if any:			
Have there been any significant new findings? ☐ Yes ☐ No			
Has there been an interim analysis? ☐ Yes ☐ No			
Have there been any changes to the approved protocol that have not been reviewed by the RANZCO HREC?			
Is there an interim Drug Safety Monitoring Board (DSMB) report available for attachment ☐ Yes ☐ No *If yes, please attach.*			
Site Summary			
Number of participants screened?			
Number of participants enrolled?			
Number of participants who withdrew or discontinued for a reason other than an adverse event:			
Number of participants who discontinued participation in the study because of an adverse event:			
Number of participants who experienced a Serious Adverse Event:			
Summarise Serious Adverse Events that occurred in the study:			
Explain why any participants terminated their participation prematurely:			

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Serious Adverse Event (SAE) Reporting
Have all serious adverse events, whether related to the study article or not, been reported to the HREC by the Principal Investigator? Yes ❑ No ❑ *Please include reports of SAEs not reported, including sponsor-generated reports*.
Informed Consent
Have all participants signed the approved Participant Information and Informed Consent Form? ☐ Yes ☐ No *If not, please explain*.
Have all participants received a copy of the Participant Information and Informed Consent Form? ☐ Yes ☐ No *If not, please explain*.
Have all participants received a copy of the RANZCO HREC guidelines for participants (FORM-HREC-006)? ☐ Yes ☐ No *If not, please explain*.
Where necessary have changes been made to the Participant Information and Informed Consent Form (e.g. Additional risks, change of Investigators?) ☐ Yes ☐ No If yes, please attach a latest copy of the Participant Information and Informed Consent Form
Please comment on the following:
Maintenance and security of records held in relation to this study:
Compliance of the study with the approved protocol, consent procedures and documentation:
Compliance with any specific conditions of approval (if relevant):
Any unforeseen events / new information that may affect continued scientific and ethical acceptability of the study?
Any complaints from participants you have received in relation to the study?
I certify that the information on this report and any attachments accompanying this report are correct.

Submitted by:	Name and signature:	Date: _ _/_ _/_ _
Telephone:	Email:	