



The Southampton Clinical Trials Unit will be closed for trials enquiries over the Easter period as follows:

From 5pm, Thursday 1 April 2021 until 9am, Monday 12 April 2021

Individual trial arrangements including Patient Registration and Randomisation listed below.

Study	Closure Information
ACCEPT	The SCTU will be closed between 5pm, Thursday 1 April 2021 until 9am, Monday 12 April 2021
	Clinical Queries
	• For clinical queries: please contact Prof. Andy Davies (direct line 023 8120 8639, email: <u>a.davies@soton.ac.uk</u> or call Southampton General Hospital switchboard on 023 8077 7222 and ask for extension 8639.
	• For urgent eligibility queries and medical emergencies: please ring Prof. Andy Davies (07976815095).
	<ul> <li>SAE Reporting         <ul> <li>Please continue to report SAEs and SUSARs by Email during this period to <u>ctu@soton.ac.uk</u>.</li> </ul> </li> </ul>
	Sample Shipment
	<b>HMDS</b> is also closed for the ACCEPT trial from Friday 2nd April 2021 – Monday 5 <sup>th</sup> April 2021 inclusive. Do <u>not</u> send samples during this time. Samples being sent on the week commencing Monday 29 <sup>th</sup> March must be sent by courier to ensure they arrive before closure.
AGILE CST-2	The SCTU will be closed between 5pm, Thursday 1 April 2021 until 9am, Monday 12 April 2021
	<ul> <li>For clinical queries: please contact Prof Saye Khoo s.h.khoo@liverpool.ac.uk</li> </ul>
	<ul> <li>SAE Reporting</li> <li>Please continue to report SAEs and SUSARs on the RAVE system, or if unable to access, by FAX during this period to 0844 774 0621.</li> </ul>





AGILE CST-	The SCTU will be closed between Frm. Thursday 1 April 2021
	The SCTU will be <b>closed</b> between <b>5pm, Thursday 1 April 2021</b>
<b>3</b> a	until 9am, Monday 12 April 2021
	For clinical queries: please contact Dr Lauren Walker
	Lauren.Walker@liverpoolft.nhs.uk
	SAE Reporting
	• Please continue to report SAEs and SUSARs on the RAVE system, or if
	unable to access, by FAX during this period to 0844 774 0621.
AGILE CST-5	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
	- For divised evering, places contact Dr Disbard Fitzgereld
	For clinical queries: please contact Dr Richard Fitzgerald
	Richard.Fitzgerald@liverpoolft.nhs.uk
	SAE Reporting
	Please continue to report SAEs and SUSARs on the RAVE system, or if
	unable to access, by FAX during this period to 0844 774 0621.
ARGO	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
	SAE Reporting
	<ul> <li>Please continue to report SAEs and SUSARs by scanning reports to</li> </ul>
	ctu@u@soton.ac.uk during this period.
BL13	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
	For URGENT clinical queries ONLY please send an email to the following email
	address:
	Please continue to report SAE's or SUSARs in the RAVE database by completing
	the eCRF which will be reviewed throughout the Easter period. If for any reason
	you are unable to access the database during this period, please report using the
	SCTU EMAIL or FAX to: ctu@soton.ac.uk or 0844 774 0621
	Southampton Tissue Bank
	- All sites sample shipments (not including Southampton) – do not ship between
	30 <sup>th</sup> March and 11 <sup>th</sup> April inclusive.
	- Southampton sample shipments ONLY – do not ship between the 31 <sup>st</sup> March and
	11 <sup>th</sup> April inclusive.



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	If a translational blood sample (STRECK tube) is collected, that cannot be shipped that day but can be shipped the next day, please place the sample in an appropriate, safe, and secure fridge at site prior to shipping the next day. Samples must be shipped <b>within 24 hours</b> of blood draw.
CONFIRM	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
	Clinical Queries
	• For <b>urgent clinical</b> queries, please contact Dean Fennell on 07870370708.
	SAE Reporting
	<ul> <li>Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements, during the Easter break.</li> </ul>
FACS	The SCTU will be closed between 5pm, Thursday 1 April 2021 until 9am, Monday 12 April 2021
HARE-40	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
	• For urgent eligibility or clinical queries please contact the Chief Investigator, Prof Christian Ottensmeier on 07879 485 676
	WISH lab is also closed for the HARE-40 trial from <b>5pm, Thursday 1<sup>st</sup> April until</b> <b>9am, Monday 12<sup>th</sup> April 2021</b> inclusive. Advance notice of any samples over this period should be sent to Katy McCann <u>K.J.McCann@soton.ac.uk</u> and Eve Currall <u>e.currall@soton.ac.uk</u> .
IELSG 37	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
	IELSG Switzerland will be <b>closed</b> for the Easter holidays from 5 PM on Thursday
	1 <sup>st</sup> April until 9 AM on Tuesday 6 <sup>th</sup> April 2021.
	• For <u>URGENT</u> queries for IELSG 37 <u>only</u> , please contact: Dr Andrew Davies
	Email: a.davies@soton.ac.uk
	Mobile: 07976815095





Southampton CIU Easter Closure Notice 2021		
IELSG 42	The SCTU will be closed between 5pm, Thursday 1st April 2021	
	until 9am, Monday 12 <sup>th</sup> April 2021	
	IELSG Switzerland will be closed on the following dates:	
	• Friday 2nd April 2021	
	<ul> <li>Friday 2nd April 2021</li> <li>Monday 5th April 2021</li> </ul>	
	<ul> <li>For URGENT clinical queries for IELSG 42 only, please contact: Dr Pam</li> </ul>	
	McKay, Email: Pam.McKay@ggc.scot.nhs.uk	
	Werkey, Ernan. <u>Farminerkey ersedet mistak</u>	
	Please contact IELSG Switzerland for queries regarding IELSG 19, 26 or 32	
MAPLE	The SCTU will be closed between Free Thursday 1 April 2021	
WAPLE	The SCTU will be closed between 5pm, Thursday 1 April 2021	
	until 9am, Monday 12 April 2021	
	<b>Patient registration:</b> Online patient registration can continue as normal. There will	
	be no paper registration service (if required) during this time.	
	Blood samples: The lab at HMDS is closed over Easter and won't receive blood	
	samples from 5pm 1 <sup>st</sup> April to 9am Tuesday 6 <sup>th</sup> April 2021 inclusive. Therefore, no	
	blood samples can be sent to HMDS by post after 31 <sup>st</sup> March. You can resume	
	sending samples as usual from Monday 5 <sup>th</sup> April.	
	Tumour samples can be sent at any time.	
MENAC	The SCTU will be closed between 5pm, Thursday 1 April 2021	
	until 9am, Monday 12 April 2021	
	For urgent <b>clinical</b> queries, please contact your PI in the first instance and then Barry	
	Laird on <u>barry.laird@ed.ac.uk</u> or 07766 503 469	
	For urgent trial queries, please contact the Norway trial team on	
	<u>menac@stolav.no</u> .	
	Please continue to report SAEs as normal.	
	Thease continue to report SALs as normal.	
Neo-AEGIS	The SCTU will be closed between 5pm, Thursday 1 April 2021	
	until 9am, Monday 12 April 2021	
	During that time, for URGENT queries ONLY please e-mail Daria Matynia, Neo-	
	AEGIS Clinical Research Associate at daria.matynia@cancertrials.ie. If your query is	
	not urgent please e-mail neoaegis@soton.ac.uk and we will reply to you on 12 <sup>th</sup>	
	April.	





	SAE Reporting
	SAE Reporting
	SAE reporting remains open and all SAEs should continue to be reported
	immediately to Pharmacovigilance@cancertrials.ie (or Fax: 00353 1 669 78 69).
Orongo II	The SCTU will be closed between From Thursday 1 April 2021
Orange II	The SCTU will be closed between 5pm, Thursday 1 April 2021 until 9am, Monday 12 April 2021
Plus	
	<b>For <u>URGENT</u> queries contact</b> Robert Fichtinger, <u>robert.fichtinger@mumc.nl</u> or contact Prof John Primrose <u>J.N.Primrose@soton.ac.uk</u> or phone 07774840909
	<ul> <li>Please continue to report SAEs by scanning reports to <u>ctu@soton.ac.uk</u> as well as Robert Fichtinger, <u>robert.fichtinger@mumc.nl</u> during this period.</li> </ul>
ProCAID	The SCTU will be closed between 5pm, Thursday 1 April 2021 until 9am, Monday 12 April 2021
	For URGENT queries ONLY please send an email to the 2 email addresses below:
	- <u>S.J.Crabb@southampton.ac.uk</u> (Chief Investigator)
	- procaid@soton.ac.uk
	Please continue to report SAE's or SUSARs by EMAIL or FAX during this period to: <a href="mailto:ctu@soton.ac.uk">ctu@soton.ac.uk</a> or 0844 774 0621
	Southampton Tissue Bank
	- Do not ship samples between 30 <sup>th</sup> March and 11th April inclusive.
	If a translational blood sample is collected, that cannot be shipped that day but can be shipped the next day, please place the sample in an appropriate, safe and secure fridge for the day the sample is held at site prior to shipping.
	If a translational blood sample is collected, that cannot be shipped for 2 or more days, please place the sample in an appropriate, safe, and secure -80 freezer and let the ProCAID Team know that this has been undertaken. DO NOT ship these frozen samples until you have received confirmation from SCTU.
	Fisher (IMP shipments)
	Fisher will not be closed over the Easter period.





	The SCTU will be closed between Free Thursday 1 April 2021
RiVa	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
	For urgent queries only, please contact Chief Investigator Sean Lim,
	S.H.Lim@soton.ac.uk
	<ul> <li>Please continue to report SAEs and SUSARs by Email during this period</li> </ul>
	to <u>ctu@soton.ac.uk</u> .
SAFA	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
	until Sant, Monday 12 April 2021
	Patients can continue to be registered during this time.
	For trial clinical and eligibility queries, please contact Professor Alison Layton
	(Email: alison.layton1@nhs.net) or Dr Miriam Santer (M.Santer@soton.ac.uk).
	Please continue to report SAE's or SUSARs by EMAIL or FAX during this period
	to: ctu@soton.ac.uk or 0844 774 0621
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SupportBack2	The SCTU will be closed between 5pm, Thursday 1 April 2021
	until 9am, Monday 12 April 2021
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	Please continue to report SAEs by FAX during this period to 0844 774
	0621.

All staff of the SCTU would like to thank everyone for their kind assistance and hard work.