

Southampton CTU Christmas Closure Notice 2018

The Southampton Clinical Trials Unit will be closed for trials enquiries over the Christmas period

From 5pm, Friday 21st December 2018
until 9am, Wednesday 2nd January 2019

Individual trial arrangements including Patient Registration and Randomisation listed below.

Study	Closure Information
<p>ACCEPT</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>Clinical Queries</p> <ul style="list-style-type: none"> • For clinical queries: please contact Professor Andy Davies (direct line 023 8120 8639, email: a.davies@soton.ac.uk or call Southampton General Hospital switchboard on 023 8077 7222 and ask for extension 8639. • For urgent eligibility queries and medical emergencies: please ring Professor Andy Davies (07976815095). <p>SAE Reporting</p> <ul style="list-style-type: none"> • Please continue to report SAEs and SUSARs by FAX during this period to 0844 774 0621. <p>Drug Ordering</p> <p>Deadline for Drug Ordering:</p> <p>Almac's last shipment date for drug orders is Wed 19th December 2018, any order received from 20th December 2018 cannot be guaranteed to be delivered. Shipments start again from the 2nd January 2018.</p> <p>Sample Shipment</p> <p>HMDS is closed for the ACCEPT trial from the 25th December to 26th December and the 1st January.</p> <ul style="list-style-type: none"> • Tumour samples – do not send between 24th to 26th December inclusive and 31st December to 1st January inclusive. If sent from the 27th to 28th December please ensure they are shipped by courier. • Blood samples – do not send between 24th to 26th December inclusive and 31st December to 1st January inclusive. If sent from the 27th to 28th

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	<p>December please ensure they are shipped by courier for same day delivery.</p> <p>WISH Laboratory is closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019.</p> <ul style="list-style-type: none"> ALL WISH Samples sent after the 19th December must be couriered to the following address: <p style="text-align: center;">Tom Hart Wellcome Trust Clinical Research Facility University Hospital Southampton NHS Foundation Trust Mailpoint 218 Southampton General Hospital Tremona Road Southampton SO16 6YD</p> <p>PATIENTS CAN CONTINUE TO BE REGISTERED ON THE RAVE DATABASE DURING THIS TIME</p>
<p>ARGO</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>Clinical Queries</p> <ul style="list-style-type: none"> For clinical queries: please contact Professor Andy Davies (direct line 023 8120 8639, email: a.davies@soton.ac.uk or call Southampton General Hospital switchboard on 023 8077 7222 and ask for extension 8639. For urgent eligibility queries and medical emergencies: please ring Professor Andy Davies (07976815095). <p>SAE Reporting</p> <ul style="list-style-type: none"> Please continue to report SAEs and SUSARs by FAX during this period to 0844 774 0621. <p>Drug Ordering</p> <p>Deadline for Drug Ordering:</p> <p>The last day to order IMP prior to Christmas closures will be <u>1pm 18th December 2018</u>, any orders received after this time will not be processed until January 2nd when the SCTU reopens, and will arrive at site on 8th January.</p> <p>Sample Shipment</p>

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	<p>HMDS is closed for the ARGO trial from the 25th December to 26th December and the 1st January.</p> <ul style="list-style-type: none"> • Tumour samples – do not send between 24th to 26th December inclusive and 31st December to 1st January inclusive. If sent from the 27th to 28th December please ensure they are shipped by courier. • Blood samples – do not send between 24th to 26th December inclusive and 31st December to 1st January inclusive. If sent from the 27th to 28th December please ensure they are shipped by courier for same day delivery. <p>WISH Laboratory is closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019.</p> <ul style="list-style-type: none"> • <u>ALL</u> WISH Samples sent after the 19th December must be couriered to the following address: <p style="text-align: center;">Tom Hart Wellcome Trust Clinical Research Facility University Hospital Southampton NHS Foundation Trust Mailpoint 218 Southampton General Hospital Tremona Road Southampton SO16 6YD</p> <p style="text-align: center;">PATIENTS CAN CONTINUE TO BE REGISTERED ON THE RAVE DATABASE DURING THIS TIME</p>
<p>CONFIRM</p>	<p>The SCTU will be closed from 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>Please register patients on the RAVE database and fax/email through the confirmation of consent form as usual. Patients may still be randomised on Tenalea over Christmas.</p> <p>For urgent eligibility queries, please contact the Chief Investigator Professor Dean Fennell by email df132@leicester.ac.uk or text 07870 370708</p>
<p>FORECAST</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>Patient registrations - During this time please register patients by email as usual.</p>

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	<p>For URGENT FORECAST Trial queries only please contact Zoe Nicholas by email Zoe.Nicholas@uhs.nhs.uk or call 023 8120 8538</p>
HARE-40	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <ul style="list-style-type: none"> For urgent eligibility or clinical queries please contact the Chief Investigator, Prof Christian Ottensmeier on 07879 485 676
HATRIC	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>The last day for HATRIC recruitment will be Friday 21st December 2018.</p> <p>Please send all registration documents for patients recruited up to the 21st December 2018 to the SCTU by noon on 24th December 2018 so that we can process them before Christmas.</p> <p>Please continue to report SAEs by FAX during this period to 0844 774 0621</p> <p>For URGENT medical queries ONLY please contact:</p> <p>Chief Investigator Professor Mike Moore on the number given in the HATRIC Christmas Closure email sent to all sites on 12th December 2018.</p>
FACS	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p>
IELSG 37	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>Clinical Queries</p> <ul style="list-style-type: none"> For clinical queries: please contact Professor Andrew Davies (direct line 023 8120 8639, email: a.davies@soton.ac.uk or call Southampton General Hospital switchboard on 023 8077 7222 and ask for extension 8639. For urgent eligibility queries and medical emergencies: please ring Professor Andy Davies (07976815095). <p>SAE Reporting</p> <p>Please continue to report SAEs to IELSG</p> <p>IELSG will be closed from Dec 24th – Dec 26th , Dec 31st and Jan 1st</p>

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<p>IELSG 32/42</p>	<p>The SCTU will be closed from 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <ul style="list-style-type: none"> • For URGENT queries for IELSG 32 & 42 only please contact: <ul style="list-style-type: none"> 24th Dec – Dr Jeff Smith Email: jeffery.smith@nhs.net 27th /28th Dec – Dr Kim Linton or Dr Pam McKay Email: Kim.M.Linton@manchester.ac.uk Email: Pam.McKay@ggc.scot.nhs.uk Dec 31st onwards - Dr Kate Cwynarski (Dec 31st onwards) Email: kate.cwynarski@nhs.net Mobile : 07870638852 <p>Please contact IELSG Switzerland for queries regarding IELSG 32 (ielsg@eoc.ch)</p> <p>IELSG will be closed from Dec 24th – Dec 26th , Dec 31st and Jan 1st</p>
<p>MAPLE</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>Online patient registration can continue as normal. There will be no registration service between 5pm on Friday 21st December 2018 to 9am on Wednesday 2nd January 2019 inclusive.</p> <p>For eligibility queries: All emails regarding eligibility queries will be answered when SCTU reopens on 2nd January 2019. Please email maple@soton.ac.uk</p> <p><u>Sending tumour and blood samples to HMDS during the holiday period:</u></p> <ul style="list-style-type: none"> • Tumour blocks can be sent at any time • Blood samples can be sent between Christmas and New Year as long as they arrive within the normal working days: <ul style="list-style-type: none"> ○ Up to and including Wednesday 19th December, blood samples can be sent in a safe box ○ on Thursday 20th December – use a courier (SCTU does not cover these costs) ○ Do not send bloods from Friday 21st December until Wednesday 26th December inclusive or on Friday 28th December. ○ For bloods to be sent on Thursday 27th December or Monday 31st December - use a courier (SCTU does not cover these costs) ○ You can start sending blood samples as per usual on Wednesday 2nd January

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<p>MENAC</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>For urgent clinical queries, please contact your PI in the first instance and then Barry Laird on barry.laird@ed.ac.uk or 07766 503 469</p> <p>For urgent trial queries, please contact the Norway trial team on menac@stolav.no.</p> <p>Please continue to report SAEs as normal.</p>
<p>Neo-AEGIS</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>For URGENT queries ONLY please contact Cancer Trials Ireland Clinical Project Manager, Aoife Shannon: aoife.shannon@cancertrials.ie</p> <p>Patient Registrations</p> <ul style="list-style-type: none"> • Please Note: TRIALS-IE will be closed between 22nd December and 30th December. Last patient registration will occur on the 21st December by 5pm and will follow the schedule below: <ul style="list-style-type: none"> - Closed: 22 Dec – 30 Dec 2018 - Open: 31 Dec 2018 - Closed: 01 Jan 2019 - Open: 02 Jan 2019 onwards • When emailing a Patient Registration Form to TRIALS-IE please ensure that you send to ALL of the following; <ul style="list-style-type: none"> ○ TRIALS-IE Patient Registration: patientregistrations@cancertrials.ie ○ SCTU: neoaegis@soton.ac.uk ○ TRIALS-IE Project Manager: Aoife.shannon@cancertrials.ie • The TRIALS-IE Patient Randomisation Service will be available on the usual fax number and email address whilst the SCTU is closed. <p>SAE Reporting</p> <ul style="list-style-type: none"> • Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements, during the Christmas break. <ul style="list-style-type: none"> ○ Cancer Trials Ireland Pharmacovigilance Unit Fax: 00-353-1-6697869 ○ E-mail address: pharmacovigilance@cancertrials.ie
<p>Orange II Plus</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>For URGENT queries contact Robert Fichtinger, robert.fichtinger@mumc.nl</p> <ul style="list-style-type: none"> • For trial clinical queries, please contact Chief Investigator Professor John Primrose via email: J.N.Primrose@soton.ac.uk

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	<ul style="list-style-type: none"> Please continue to report SAEs by scanning reports to ctu@soton.ac.uk as well as Robert Fichtinger, robert.fichtinger@mumc.nl during this period.
<p>ProCAID</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>For URGENT queries ONLY contact Southampton General Hospital switchboard on 023 8077 7222 and ask to be put through to Dr Simon Crabb (ProCAID Chief Investigator).</p> <p>If unblinding is being considered for a patient, please contact Dr Crabb on 07972 244810 prior to undertaking unblinding on the IWRS (unless it is a medical emergency and unblinding is required immediately).</p> <p>Please continue to send SAE/SUSAR/SAR Reports by email or fax during this period to ctu@soton.ac.uk or 0844 774 0621.</p> <p><u>Southampton Tissue Bank:</u></p> <p>- All sites sample shipments – the last posting date is Friday 14-Dec-2018 and the first posting date is 01-Jan-2019.</p> <p>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.</p> <ul style="list-style-type: none"> ➤ Example: translational blood sample collected on 31st December, place in fridge immediately and ship as normal to Tissue Bank on the 1st January. <p>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.</p> <ul style="list-style-type: none"> ➤ Example: translational blood sample collected between the 15th December and 30th December, 2017, place in an appropriate, safe and secure -80 freezer. Let the ProCAID Team know about this and do not ship the sample until you have received confirmation from SCTU. <p><u>Fisher (IMP shipments):</u></p> <p>Fisher will be closed for IMP shipments as follows:</p> <ul style="list-style-type: none"> • 22-Dec-2018 to 26-Dec-2018 inclusive – No shipping • 29-Dec-2018 to 30-Dec-2018 inclusive – No shipping • 01-Jan-2019 – No shipping

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	<p><u>IWRS (Cenduit)</u> For any Cenduit queries, please contact the Helpdesk on 01403 342316 (open 24/7, 365).</p> <p>Randomisation is undertaken using the ProCAID IWRS (Cenduit), available 24 hours a day 365 days a year. You <u>DO NOT</u> need to complete the ProCAID Phase II Patient Eligibility and Randomisation Form prior to randomisation.</p>
<p>REMoDL-B</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>For urgent queries and medical emergencies ONLY: please ring Professor Andy Davies (07976815095).</p>
<p>RiVa</p>	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>Clinical Queries</p> <ul style="list-style-type: none"> • For clinical queries, urgent eligibility and medical emergencies : please contact the Chief Investigator Sian Lim, S.H.Lim@soton.ac.uk <p>SAE Reporting</p> <ul style="list-style-type: none"> • Please continue to report SAEs and SUSARs by FAX during this period to 0844 774 0621. <p>Drug Ordering</p> <p><u>Deadline</u> for Drug Ordering:</p> <p>The last day to order IMP prior to Christmas closures will be 16th December 2018, any orders received after this time may not be delivered until the New Year.</p> <p>WISH Laboratory is closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019.</p> <ul style="list-style-type: none"> • <u>ALL</u> WISH Samples sent after the 19th December must be couriered to the following address: <p style="text-align: center;">Tom Hart Wellcome Trust Clinical Research Facility University Hospital Southampton NHS Foundation Trust Mailpoint 218 Southampton General Hospital Tremona Road Southampton</p>

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	PATIENTS CAN CONTINUE TO BE REGISTERED ON THE RAVE DATABASE DURING THIS TIME
SoMOSA	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>For trial clinical queries, please contact Chief Investigator Ratko Djukanovic via email: R.Djukanovic@soton.ac.uk or telephone: 07540 671212.</p>
SPIRE	<p>The SCTU will be closed between 5pm, Friday 21st December 2018 until 9am, Wednesday 2nd January 2019</p> <p>For Urgent queries ONLY: contact Southampton General Hospital switchboard on 023 8077 7222 and ask to be put through to Dr Simon Crabb.</p>

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