

## Christmas Closure Notice 2014/15

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

From 4pm, Wednesday 24th December 2014  
until 9am, Monday 5th January 2015

Individual trial arrangements including Patient Registration and Randomisation listed below.

Study	Closure Information
<b>BREATHE</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24th December 2014 to 9am on Monday 5th January 2015 inclusive.</p> <p>There will be <b>no</b> randomisation service between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <ul style="list-style-type: none"> <li>For <b>URGENT</b> medical queries <b>ONLY</b>: please contact: Chief Investigator Professor Mike Thomas on: <b>0775 371 9867</b></li> </ul>
<b>BIOSTENT</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p>
<b>COAST</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive. You will <b>not</b> be able to obtain a screening number during this period.</p> <p>The Tissue bank will be <b>closed</b> between 4pm on Tuesday 23<sup>rd</sup> December 2014 until 9am on Monday 5<sup>th</sup> January 2015. However, to ensure samples arrive before the Christmas close down, please <b>do not post</b> samples after Tuesday 16<sup>th</sup> December 2014.</p> <p>The Audiology department at the Royal South Hants Hospital will be closed between 4pm on Tuesday 23<sup>rd</sup> December 2014 and 9am on Monday 29<sup>th</sup> December 2014. They will also be closed on Thursday 1<sup>st</sup> January 2015. You will be unable to book hearing assessments during this period. If you use a local facility for hearing assessments, please check with them directly to confirm closure dates for this period.</p> <p>For <b>Urgent queries ONLY</b>; contact Southampton General Hospital switchboard on <b>023 8077 7222</b> and ask to be put through to Dr Simon Crabb.</p> <ul style="list-style-type: none"> <li>Please continue to report SAE's or SUSARs by FAX during this period to <b>0844 774 0621</b></li> </ul>
<b>COPPI</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p>

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<b>EPOC B</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <p>There will be <b>no</b> randomisation service between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <p>The Tissue bank will be <b>closed</b> between 4pm on Monday 23<sup>rd</sup> December 2013 and 9am on Thursday 2<sup>nd</sup> January 2014. However, to ensure samples arrive before the Christmas close down, please do not post samples after Wednesday 18<sup>th</sup> December 2013.</p> <ul style="list-style-type: none"> <li>• <b>For URGENT queries ONLY:</b> contact University College London Hospitals switchboard on <b>0845 1555 000</b> and ask to be put through to Dr John Bridgewater.</li> <li>• <b>Please continue to report SAEs or SUSARs by FAX during this period to 0844 774 0621</b></li> </ul>
<b>FACS</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <p><b><u>**Please note that Alice Fuller in Oxford, will also not be contactable during this period**</u></b></p> <ul style="list-style-type: none"> <li>• <b>For URGENT clinical queries ONLY:</b> contact Southampton General Hospital switchboard on <b>023 8077 7222</b> and ask to be put through to Professor John Primrose.</li> </ul>
<b>Gem-TIP</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p>
<b>ICE</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <ul style="list-style-type: none"> <li>• <b>Please continue to report SAEs or SUSARs by FAX during this period to 0844 774 0621</b></li> <li>• <b>For URGENT queries ONLY,</b> please contact: Professor Christian Ottensmeier, Chief Investigator on <b>07788 411 462</b></li> </ul>
<b>IELSG 19, 26, 32 &amp; IELSG 37</b>	<p>The SCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <p>IELSG Switzerland will be closed from noon on 24<sup>th</sup> December 2014 - 28<sup>th</sup> December 2014 inclusive and then from noon on 31<sup>st</sup> December 2014 – 4<sup>th</sup> January 2015 inclusive.</p>

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	<p>IELSG Switzerland will also be closed on Tuesday, 6<sup>th</sup> January. There will be <b>no</b> randomisation service for <b>IELSG 37</b> with the exception of <b>Friday, 2 January 2015, only, (for randomisations please email <a href="mailto:ielsg@ticino.com">ielsg@ticino.com</a>)</b></p> <ul style="list-style-type: none"> <li>• For <b>URGENT</b> queries for <b>IELSG 32 only</b>, please contact: Dr Chris Fox on the following dates: Monday, 22nd December 2014 – Sunday, 28th December, 2014 Email: <a href="mailto:christopher.fox@nhs.net">christopher.fox@nhs.net</a> Mobile: <b>07951748784</b></li> </ul> <p>Dr Kate Cwynarski on the following dates: Week commencing Monday 29th December 2014 Email: <a href="mailto:kate.cwynarski@nhs.net">kate.cwynarski@nhs.net</a> Tel: <b>0207 317 7514</b> Mobile: <b>07870638852</b></p> <ul style="list-style-type: none"> <li>• For <b>URGENT</b> queries for <b>IELSG 37 only</b>, please contact: Dr Andrew Davies Email: <a href="mailto:a.davies@soton.ac.uk">a.davies@soton.ac.uk</a> Mobile : <b>07976815095</b> Tel: <b>023 8120 8639 (Medical Secretary - Lynn Mooney)</b></li> </ul> <p>Please contact IELSG for queries regarding IELSG 19 or 26</p>
<p><b>New EPOC</b></p>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <ul style="list-style-type: none"> <li>• For <b>URGENT</b> queries <b>ONLY</b>: contact Southampton General Hospital switchboard on <b>023 8077 7222</b> and ask to be put through to Professor John Primrose.</li> <li>• Please continue to report SAEs or SUSARs by FAX during this period to <b>0844 774 0621</b></li> </ul>
<p><b>Orange II Plus</b></p>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <ul style="list-style-type: none"> <li>• For <b>URGENT</b> queries <b>ONLY</b>: contact Southampton General Hospital switchboard on <b>023 8077 7222</b> and ask to be put through to Professor John Primrose.</li> <li>• Please continue to report SAEs or SUSARs by scanning reports to both Robert Fichtinger, <a href="mailto:robert.fichtinger@mumc.nl">robert.fichtinger@mumc.nl</a> and Marjan Klinkert, <a href="mailto:marjan.klinkert@mumc.nl">marjan.klinkert@mumc.nl</a> during this period.</li> </ul>
<p><b>PCV13 in ALL</b></p>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <ul style="list-style-type: none"> <li>• For <b>URGENT</b> queries <b>ONLY</b>, please contact Chief Investigator Dr. Juliet Gray</li> </ul>

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on **07901 507929**.

- **Please continue to report SAEs or SUSARs by FAX during this period to 0844 774 0621**

### ProCAID

The **SCTU** will be **closed** between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive. You will **not** be able to obtain a screening number during this period.

**Fisher** will be closed for IMP shipments as follows:

Saturday 20<sup>th</sup> December 2014 to 21<sup>st</sup> December 2014

Thursday 25<sup>th</sup> December 2014 to Sunday 28<sup>th</sup> December 2014

Thursday 1<sup>st</sup> January 2015

### Covance PK Kits and Sample Shipment

Mon 22 Dec 2014	Tue 23 Dec 2014	Wed 24 Dec 2014	Thu 25 Dec 2014	Fri 26 Dec 2014	Sat 27 Dec 2014	Sun 28 Dec 2014
Last pick-up day this week for <b>48hr</b> transit time from site to CCLS	Last pick-up day this week for <b>24hr</b> transit time from site to CCLS ***** <b>48hr</b> transit time Do not ship samples	<b>Do not ship samples</b>	<b>Christmas Day</b> <b>Do not ship samples</b>	Last pick-up day this week for <b>24hr</b> transit time from site to CCLS ***** <b>48hr</b> transit time Do not ship samples	All sites Normal week-end schedule	All sites Normal week-end schedule
29 Dec 2014	30 Dec 2014	31 Dec 2014	1 Jan 2015	2 Jan 2015	3 Jan 2015	5 Jan 2015
Last pick-up day this week for <b>48hr</b> transit time from site to CCLS	Last pick-up day this week for <b>24hr</b> transit time from site to CCLS ***** <b>48hr</b> transit time Do not ship samples	<b>Do not ship samples</b>	<b>New Year's Day</b> <b>Do not ship samples</b>	Last pick-up day this week for <b>24hr</b> transit time from site to CCLS ***** <b>48hr</b> transit time Do not ship samples	All sites Normal week-end schedule	All sites Normal week-end schedule

Frozen specimens should not be shipped on the day before the observed holiday for 24hr sites, or two days prior to the holiday for 48hr sites, but should be sent on the next available business day.

The **Tissue Bank** will be **closed** between 4pm on Tuesday 23<sup>rd</sup> December 2014 until 9am on Monday 5<sup>th</sup> January 2015. However, to ensure samples arrive before the Christmas close down, please **do not post** samples after Tuesday 16<sup>th</sup> December 2014.

For **Urgent queries ONLY**; contact Southampton General Hospital switchboard on **023 8077 7222** and ask to be put through to Dr Simon Crabb.

- **Please continue to report SAE's or SUSARs by FAX during this period to 0844 774 0621**

### REMoDL-B

The Southampton CTU will be **closed** between 4pm on Wednesday 24<sup>th</sup> December and 9am on 5<sup>th</sup> January 2015. **There will be no registration service between these times.**

- **For clinical queries:** please contact Dr Andy Davies (direct line 02381208639,

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email: [a.davies@soton.ac.uk](mailto:a.davies@soton.ac.uk) or call Southampton General Hospital switchboard on 023 8077 7222 and ask for extension 8639.

- **For eligibility & treatment queries:** contact by email: Professor Peter Johnson [johnsonp@soton.ac.uk](mailto:johnsonp@soton.ac.uk) or Dr Andy Davies [a.davies@soton.ac.uk](mailto:a.davies@soton.ac.uk)
- **For urgent queries and medical emergencies:** please ring Professor Peter Johnson (07887651259) or Dr Andy Davies (07976815095).
- **Please continue to report SAEs and SUSARs by FAX during this period to 0844 774 0621.**

### Deadline for drug ordering

Drug orders for delivery **Prior to the Christmas period** must be sent to the Southampton CTU by 12:00 Monday 8<sup>th</sup> December. Any drug orders sent to the Southampton CTU after Monday 8<sup>th</sup> December may not arrive prior to the New Year, please ensure that you plan accordingly to ensure you have sufficient Velcade for any patients over this period.

### Deadline for sending tumour blocks to HMDS:

HMDS will also be closed between Christmas and new year for receiving samples.

Tumour blocks can be sent during the Christmas period, however there are deadlines for specific cycle 2 dates, please ensure you continue to send the Molecular Profiling consent form with the tumour blocks.

Cycle 2 date	Deadline
Up to and including 7 <sup>th</sup> January	Should be with HMDS by 19 <sup>th</sup> December
Between 8 <sup>th</sup> – 14 <sup>th</sup> January	Should be with HMDS by 2 <sup>nd</sup> January

From 8<sup>th</sup> December please discuss all potential REMoDL-B patients with the Southampton CTU REMoDL-B team so that we can insure that the deadlines for HMDS and drug orders can be met.

### Bloods/EDTA samples to HMDS

Please do not send EDTA samples to HMDS between 24<sup>th</sup> December and the 1<sup>st</sup> January.

**PATIENTS CANNOT BE REGISTERED WHEN THE SOUTHAMPTON CTU IS CLOSED & ALL REMoDL-B PATIENTS MUST BE REGISTERED BEFORE THE START OF CYCLE 1.**

**SAKK 08/11**

The UoSCTU will be **closed** between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.

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	<p>For trial clinical queries, please contact Chief Investigator Dr Simon Crabb <a href="mailto:s.j.crabb@soton.ac.uk">s.j.crabb@soton.ac.uk</a></p>
<b>SCHRIFT</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <ul style="list-style-type: none"> <li>• Please continue to report SAEs or SUSARs by FAX during this period to <b>0844 774 0621</b></li> </ul>
<b>SPUTNIK</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <p>There will be <b>no</b> registration service between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive</p> <ul style="list-style-type: none"> <li>• For <b>URGENT</b> trial queries <b>only</b> please contact Professor Steve George by email <a href="mailto:pluto@soton.ac.uk">pluto@soton.ac.uk</a></li> </ul>
<b>WIN</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <ul style="list-style-type: none"> <li>• Please continue to report SAEs or SUSARs by FAX during this period to <b>0844 774 0621</b></li> </ul>
<b>Hip Op</b>	<p>The UoSCTU will be <b>closed</b> between 4pm on Wednesday 24<sup>th</sup> December 2014 to 9am on Monday 5<sup>th</sup> January 2015 inclusive.</p> <ul style="list-style-type: none"> <li>• Normal randomisation service will be available via TENALEA website: <a href="https://prod.tenalea.net/stn/dm/">https://prod.tenalea.net/stn/dm/</a></li> <li>• Please continue to report SAEs or SUSARs by FAX during this period to <b>0844 774 0621</b></li> <li>• For <b>URGENT</b> queries <b>ONLY</b>, please contact: Professor Nicholas Clarke, Chief Investigator on 07785 252009</li> </ul>

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

We would like wish you a very Merry Christmas  
and a Happy New Year for 2015!

UKCRC  
Registered  
Clinical  
Trials Units



UNIVERSITY OF  
Southampton

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