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

**From 5pm, Wednesday 22nd December 2021  
until 9am, Tuesday 4th January 2022**

**Individual trial arrangements including Patient Registration and Randomisation listed below.**

|  |  |
| --- | --- |
| **Study** | **Closure Information** |
| **ACCEPT** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  **Clinical Queries**     * **For clinical queries:** please contact Prof. Andy Davies (direct line 023 8120 8639, 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 urgent eligibility queries and medical emergencies:** please ring Prof. Andy Davies (07976815095).   **SAE Reporting**   * **Please continue to report SAEs and SUSARs by EMAIL or FAX during this period to:**   [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) **or 0844 774 0621** |
| **AGILE CST-2** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**   * **For urgent clinical queries:** please contact Prof Saye Khoo [khoo@liverpool.ac.uk](mailto:khoo@liverpool.ac.uk) * **For all queries contact** [**e.l.knox@soton.ac.uk**](mailto:e.l.knox@soton.ac.uk)– trial management cover for the whole of the Christmas closure period, and will coordinate contact with the CI   **SAE Reporting**   * **Please continue to report SAEs and SUSARs on the RAVE system, or if unable to access, by FAX on 0844 774 0621 or by email to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) **during this period.** |
| **AGILE CST-5** | The SCTU will be closed between 5pm, Wednesday 22nd December 2021  until 9am, Tuesday 4th January 2022  • **For clinical queries:** please contact Dr Richard FitzGerald by email:  Richard.Fitzgerald@liverpoolft.nhs.uk  **SAE Reporting**  • **Please continue to report SAEs and SUSARs on the RAVE system, or if**  **unable to access, by EMAIL to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) **or FAX to 0844 774 0621 during this period.** |
| **BL13** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  **For URGENT clinical queries ONLY** please send an email to the following email address:  - S.J.Crabb@southampton.ac.uk (Chief Investigator)  **Please continue to report SAE’s or SUSARs in the RAVE database** by completing the eCRFwhich will be reviewed throughout the Festive 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 20th December and 3rd January inclusive.  **- Southampton sample shipments ONLY** – do not ship between the 22nd December and 3rd January inclusive.  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 **within 24 hours** of blood draw. |
| **CONFIRM** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  **Clinical Queries**   * For **urgent clinical** queries, please contact Dean Fennell on 07870370708.   **SAE Reporting**   * Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements, during the Christmas break. |
| **CONTRACT 2** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  **For URGENT clinical queries ONLY** please send an email to Nigel Hall [n.j.hall@soton.ac.uk](mailto:n.j.hall@soton.ac.uk) (Chief Investigator)  **SAE Reporting**  Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements, during the Christmas break. |
| **ELEVATE** | The SCTU will be **closed** between **5 pm, Wednesday 22nd December 2021 until 9 am, Tuesday 4th January 2022.**  **SAE Reporting**   * Please continue to report all Serious Adverse Events (SAEs) in accordance with protocol requirements, during the Christmas break.   **CMDL** will be closed between **5 pm, Thursday, 23rd December 2021 until 9 am, Tuesday 4th January 2022 and are not able to receive samples during this time.** You can resume sending samples as usual from Tuesday, 4th January 2022.  For **urgent queries on ELEVATE only**, please contact:  Dr Elizabeth Smyth  Mobile: 07463717859 Email: [Elizabeth.Smyth@addenbrookes.nhs.uk](mailto:Elizabeth.Smyth@addenbrookes.nhs.uk) |
| **HARE-40** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**   * 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 **5pm Wednesday 22nd December 2021 until 9am, Monday 3rd January 2022** inclusive. Advance notice of any samples over this period should be sent to Katy McCann [K.J.McCann@soton.ac.uk](mailto:K.J.McCann@soton.ac.uk) and James Pickering [james.pickering@soton.ac.uk](mailto:james.pickering@soton.ac.uk). |
| **iDx Lung** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022.**  **IDx van not operating 21st Dec to ~ 11 Jan for Xmas closure and relocation to RSH** |
| **IELSG 37** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  IELSG Switzerland will be **closed** on Friday 24th and Friday 31st December 2021 and Thursday 6th and Friday 7th January 2022.  IELSG Switzerland will be **open** from 27th to 30th December 2021 and from 3rd to 5th January 2022.  For urgent emails to IESLG over the Christmas period, please use their shared inbox - [ielsg@eoc.ch](mailto:ielsg@eoc.ch).   * **For URGENT queries for IELSG 37 only**, please contact:   Dr Andrew Davies  Email:[**a.davies@soton.ac.uk**](mailto:a.davies@soton.ac.uk)  Mobile: **07976815095** |
| **IELSG 42** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  IELSG Switzerland will be **closed** on Friday 24th and Friday 31st December 2021 and Thursday 6th and Friday 7th January 2022.  IELSG Switzerland will be **open** from 27th to 30th December 2021 and from 3rd to 5th January 2022.  For urgent emails to IESLG over the Christmas period, please use their shared inbox - [ielsg@eoc.ch](mailto:ielsg@eoc.ch).   * **For URGENT queries for IELSG 32/42 only** please contact:   Dr Kate Cwynarski  Email:[**kate.cwynarski@nhs.net**](mailto:kate.cwynarski@nhs.net)  Mobile: **07870638852**  Please contact IELSG Switzerland for queries regarding IELSG 19, 26 or 32 |
| **MAPLE** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022** |
| **MENAC** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  For urgent **clinical** queries, please contact your PI in the first instance and then Barry Laird on [barry.laird@ed.ac.uk](mailto:barry.laird@ed.ac.uk) or 07766 503 469  For urgent trial queries, please contact the Norway trial team on [menac@stolav.no](mailto:menac@stolav.no).  Please continue to report SAEs as normal. |
| **Neo-AEGIS** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  During that time for **URGENT queries ONLY** please call Anna Shevlin, Neo-AEGIS Clinical Project Manager on 00353 8790 038 51  **SAE Reporting**  SAE reporting remains open and all SAEs should continue to be reported immediately to [Pharmacovigilance@cancertrials.ie](mailto:Pharmacovigilance@cancertrials.ie) (or Fax: 00353 1 669 78 69) |
| **Orange II Plus** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  **For URGENT queries  contact** Robert Fichtinger, [**robert.fichtinger@mumc.nl**](mailto:robert.fichtinger@mumc.nl%20) or contact Prof John Primrose [J.N.Primrose@soton.ac.uk](mailto:J.N.Primrose@soton.ac.uk) or phone 07774840909   * Please continue to report SAEs by scanning reports to [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) as well as Robert Fichtinger, [**robert.fichtinger@mumc.nl**](mailto:robert.fichtinger@mumc.nl) during this period. |
| **REMoDL-A** | **SCTU**  The SCTU will be closed from **5pm on Wednesday 22nd December 2021 to 9am on Tuesday 4th January 2022.**   * Patient enrolment is open as usual during this time. * **For clinical queries**: please contact Prof. Any Davies (direct line 023 8120 8639), 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 urgent eligibility queries** **and medical emergencies**: please ring Prof. Andy Davies (07976815095). * **For SAE reporting:** please continue to report SAEs and SUSARs by email to [ctu@soton.ac.uk](mailto:ctu@soton.ac.uk) or by FAX to 0844 774 0621.   **HMDS**  HMDS will be closed from **12 noon on Friday 24th December to 9am on Wednesday 29th December**. The lab will also be closed on **Monday 3rd January**, and re-open as normal from Tuesday 4th January   * Blood samples delivered by mail should be **dispatched on or before Tuesday 21st December** and must be **received by Thursday 23rd December** at the latest. Any samples posted after 21st Dec will most likely not reach the lab before closure and will be inadequate for testing. * Tumour blocks may be sent anytime throughout the Christmas and New Year period. |

|  |  |
| --- | --- |
| **RiVa** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  **For urgent queries only**, please contact Chief Investigator Sean Lim, [S.H.Lim@soton.ac.uk](mailto:S.H.Lim@soton.ac.uk)  **SAE Reporting**   * **Please continue to report SAEs and SUSARs by EMAIL or FAX during this period to:**   [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) **or 0844 774 0621.** |
| **SAFA** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**  **For trial clinical queries,** please contact Professor Alison Layton   * Phone: 07590 456 738 * Email: [alison.layton1@nhs.net](mailto:alison.layton1@nhs.net)   **Please continue to report SAE’s or SUSARs by EMAIL or FAX during this period to: ctu@soton.ac.uk or 0844 774 0621** |
| **SupportBack2** | The SCTU will be **closed** between **5pm, Wednesday 22nd December 2021 until 9am, Tuesday 4th January 2022**   * **Please continue to report SAEs by FAX during this period to 0844 774 0621 or by email to** [**ctu@soton.ac.uk**](mailto:ctu@soton.ac.uk) |

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