# NEWSLETTER

ISSUE NO 07 | JUN 2024

*(issued every 6 months)*

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| The RGIT newsletter provides updates on | ✓ Standard Operating Procedures (SOPs)<br>✓ Internal Staff updates<br>✓ Training Events<br>✓ Website Updates<br>✓ New/Updated Guidelines<br>✓ Regulatory Updates |


## Staff Updates

Chris Ente has left, and Alina Saeed is now returned.

## Quality Management System Updates

| | | |
|---|---|---|
| RGIT_SOP_001 | 13.0 | 06-Feb-24 |
| RGIT_SOP_002 | 10.0 | 06-Feb-24 |
| RGIT_SOP_004 | 10.0 | 06-Feb-24 |
| RGIT_SOP_006 | 12.0 | 06-Feb-24 |
| RGIT_SOP_007 | 12.0 | 20-Mar-24 |
| RGIT_SOP_008 | 14.0 | 14-Mar-24 |
| RGIT_SOP_011 | 10.0 | 06-Feb-24 |
| RGIT_SOP_012 | 12.0 | 05-Mar-24 |
| RGIT_SOP_013 | 9.0 | 09-Jan-24 |
| RGIT_SOP_015 | 10.0 | 14-Mar-24 |
| RGIT_SOP_016 | 20.0 | 23-May-24 |
| RGIT_SOP_019 | 10.0 | 06-Feb-24 |
| RGIT_SOP_020 | 11.0 | 09-Jan-24 |
| RGIT_SOP_021 | 9.0 | 14-Mar-24 |
| RGIT_SOP_023 | 9.0 | 09-Jan-24 |
| RGIT_SOP_025 | 9.0 | 09-Jan-24 |
| RGIT_SOP_027 | 9.0 | 12-Feb-24 |
| RGIT_SOP_029 | 9.0 | 09-Jan-24 |
| RGIT_SOP_037 | 7.0 | 06-Feb-24 |
| RGIT_SOP_042 | 3.0 | 09-Jan-24 |
| RGIT_SOP_049 | 4.0 | 09-Feb-24 |
| RGIT_GUID_010 | 2.0 | 31-May-24 |
| RGIT_GUID_013 | 9.0 | 09-May-24 |
| RGIT_GUID_030 | 1.0 | 08-Mar-24 |

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|---|---|---|
| RGIT_GUID_031 | 1.0 | 22-Mar-24 |
| RGIT_GUID_032 | 1.0 | 15-May-24 |
| RGIT_TEMP_001 | 3.0 | 06-Feb-24 |
| RGIT_TEMP_003 | 4.0 | 20-Mar-24 |
| RGIT_TEMP_004 | 2.0 | 06-Feb-24 |
| RGIT_TEMP_006 | 3.0 | 06-Feb-24 |
| RGIT_TEMP_007 | 2.0 | 06-Feb-24 |
| RGIT_TEMP_008 | 2.0 | 06-Feb-24 |
| RGIT_TEMP_011 | 3.0 | 06-Feb-24 |
| RGIT_TEMP_016 | 4.0 | 14-Mar-24 |
| RGIT_TEMP_017 | 4.0 | 14-Mar-24 |
| RGIT_TEMP_018 | 4.0 | 14-Mar-24 |
| RGIT_TEMP_023 | 3.0 | 06-Feb-24 |
| RGIT_TEMP_024 | 3.0 | 06-Feb-24 |
| RGIT_TEMP_025 | 3.0 | 06-Feb-24 |
| RGIT_TEMP_026 | 5.0 | 06-Feb-24 |
| RGIT_TEMP_027 | 7.0 | 06-Feb-24 |
| RGIT_TEMP_029 | 3.0 | 14-Mar-24 |
| RGIT_TEMP_031 | 7.0 | 30-Apr-24 |
| RGIT_TEMP_032 | 6.0 | 23-May-24 |
| RGIT_TEMP_033 | 7.0 | 23-May-24 |
| RGIT_TEMP_034 | 6.0 | 23-May-24 |
| RGIT_TEMP_035 | 2.0 | 06-Feb-24 |
| RGIT_TEMP_071 | 2.0 | 09-Feb-24 |
| RGIT_TEMP_073 | 2.0 | 14-Mar-24 |
| RGIT_TEMP_080 | 4.0 | 12-Jan-24 |

# Additional Updates

### 3yr SOP Review

The RGIT 3 yearly SOP review is approaching a close.

### Trial Registration

All new CTIMP CTAs are now submitted by using CTIS and the use of the EudraCT registry will be completely replaced by that of CTIS by 2025.

### Recent Updates

The new UK drug and device regulations are likely to be approved in parliament this Autumn and then be implemented fully by August 2025. Edge is now live and should be used in place of Documas following a transition stage lasting until June 2024.

### HRA

The Declaration of Helsinki is a foundation reference document for both the UK Clinical Trials legislation and the UK Policy Framework for Health and Social Care Research. A consultation on revisions to the Declaration of Helsinki has been recently launched by the WMA.

CAG have recently recruited new members with expertise to manage the use of AI when working with confidential data. Advice on whether Section 251 applies should be especially sought from CAG members when data without consent are used (recent updates; pre-application checklist; guidance for CAG applicants). More on CAG applications may be also found on the ICO website.

The HRA promote transparency by requiring and/or encouraging registration and/or publication of results, and communication of study outcomes to participants: the ongoing consultation on make it public has evidenced that there is strong agreement on the importance of informing participants, 'with several pointing out that information needs to be accessible and easy to

understand'(Naho Yamazaki). The role of the sponsor in this seems to become fundamental: better understanding of this is available in the Research Transparency Annual Report 2022/23.

The government's response to Professor Tickell's independent review of the research bureaucracy plans to improve research efficiency and productivity in research in line with the work that the HRA has already carried out on this. Recent updates on this have been the formal implementation of the quality standards and design, and review principles (which have become mandatory on 1 Dec 2023) and the publication of the guidance on decentralised trial methods.

The feedback deadline following the call for comments and suggestions on study template arrangements was on 13 May 2024, this has been extended to 3 June 2024. Results should be shared soon!

Important updates by the HRA sent out recently have been: update to the organisation information documents; clarification of HRA policy on the registration of CTIMPs taking place in the UK and EU.

The HRA has now moved their training activities to the National Institute for Health and Care Research which has been relaunched and improved at Learning for Involvement website.

The MHRA has published a statement on the draft policy for recognition by the UK of international regulators' approvals of medical devices.

The HRA has informed that, from 1 June 2024, study teams of research approved by RECs in England and Wales will no longer be required to submit annual progress reports and are expected to acknowledge SUSARS and annual safety reports differently from the standard procedure.

- *Researchers will still need to report anything that materially affects the ethics of an application by the current expectation and will still need to submit an end of study declaration and final study report.*
- *Fatal and life-threatening SUSARS need to continue to be reported to the Medicine and Healthcare products Regulatory Agency (MHRA) and the REC as soon as possible. SUSARS and safety reports for CTIMPs which were approved by combined review should be submitted to the MHRA only. If the safety report requires action, the MHRA will instruct the study team to submit a substantial amendment to the REC.*
  *Any other SUSARS or annual safety report submitted to the HRA will be acknowledged by email by the REC. The submitted cover report for the SUSAR or annual safety report will not be signed and returned, the email will act as the formal acknowledgement.*

# Training Updates

## TRAINING

The college encourages the use of online resources for learning, e-learning. Also, there are suggestions for training opportunities such as online training modules or training platforms as well as the use of other MHRA resources. The creation of a shared training folder in the RGIT shared area has been also proposed. Training is a key part of the RGIT role within the college and part of this is also devoted to training college researchers. Some examples of online training resources have been listed here below.

### RESEARCH INTEGRITY & ETHICS AT IMPERIAL COLLEGE E-LEARNING

The RGIT reminds that the 'Research Integrity & Ethics at Imperial College' e-learning course is mandatory for all new staff starters at Imperial, including Clinical and Clinical Research Academics, and Research Academics. This self-guided 90-minute training covers the integrity and ethics of research at the College, and it is part of the RGIT training webpage. As explained in the previous issues of this newsletter, we encourage all staff who want to refresh in research integrity to take it, as this helps to understand the role of RGIT within the college Research Approval Process and the REF (research excellence framework).

## ADDITIONAL RESOURCES: RESEARCH INTEGRITY & ETHICS RELATED E-LEARNING

RGIT workshops on research in the NHS are being held on a quarterly basis. The workshops are run between 9.30am and 1pm. To register interest please email rgit_training@imperial.ac.uk.

The RGIT team is planning to run internal knowledge sharing sessions though these would be reserved to the RGIT members only.