

NEWSLETTER

ISSUE NO 06 | DEC 2023



(issued every 6 months)

<p>The RGIT newsletter provides updates on</p>	<ul style="list-style-type: none"> ✓ Standard Operating Procedures (SOPs) ✓ Internal Staff updates ✓ Training Events ✓ Website Updates ✓ New/Updated Guidelines ✓ Regulatory Updates
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Staff Updates

Krishna Askoolam, a clinical trial monitor, has left and Santosh Singh has joined the RGIT monitoring team. Naomi Gardner has returned to work - Welcome back Naomi!

Quality Management System Updates

RGIT_GUID_004	Version 3.0 on 05-Sep-23
RGIT_GUID_009a	Version 2.3 on 01-Jul-22
RGIT_GUID_009b	Version 2.3 on 01-Jul-22
RGIT_GUID_013	Version 8.0 on 20-Oct-23
RGIT_GUID_023	Version 4.0 on 05-Dec-23
RGIT_GUID_024	Version 3.0 on 05-Dec-23
RGIT_GUID_025	Version 2.0 on 05-Dec-23
RGIT_GUID_026	Version 4.0 on 05-Dec-23
RGIT_GUID_028	Version 2.0 on 05-Dec-23
RGIT_GUID_029	Version 3.0 on 05-Dec-23
RGIT_TEMP_021	Version 15.0 on 27-Jun-23
RGIT_TEMP_022	Version 5.0 on 22-Nov-2023

3yr SOP Review

The RGIT 3 yearly SOP review has started, and it is currently still in progress. As a result of the increase in queries, during this review, the review process has not been completed in full yet. The SOPs and

applicable templates that still need to be updated will be uploaded on the RGIT SOP website at the dedicated link after approval by the HoRGIT.

Trial Registration

The assessment of Imperial and Imperil NHS Trust study registry records is currently performed by the QA Facilitator. The use of the EudraCT registry has been recently restricted as a result of the new CTIS system being in place. Please note that from 31 January 2023, all new CTIMP CTAs must be submitted by using CTIS. Also, the addition of new member states (MS) in a study will only be possible after that the trial has been transitioned, that is by using the CTIS register. Local CTIMPs will be automatically registered in the ISRCTN public registry through the CWOW scheme.

HRA

The [Quality Standards and Design and Review Principles](#) were introduced in Sept 2023 and have become mandatory on [1 Dec 2023](#).

The HRA have published [guidance on decentralised trial methods](#).

The HRA have updated the [guidance for CAG Applicants](#).

The NIHR learn platform will bring together the learning from the HRA and the NIHR in one place and will replace the former LMS by the next March (2024). This will enable the HRA to deliver training for a broad range of professionals such as HRA staff, researchers and confidentiality advisory group members, public involvement network members and research ethics committee members. All courses will be available in the new platform, which will also provide training for all users. More information on this is available from the [HRA Learning & Development Team](#).

According to YouGov, 88% of people believe that a diverse mix of participants in health and social care research is helpful. See how is diversity currently prioritised in health and social care research by Naho Yamazaki, [Deputy Director of Policy and Partnerships](#).

[Blog by Alastair Nicholson](#), reflecting on the news that the performance of the National Contract Value Review (NCVR) process has recently improved (study set-up milestones have been over 100 days quicker).

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.