

NEWSLETTER

RESEARCH GOVERNANCE AND INTEGRITY TEAM Imperial College London

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ST MARY'S HOSPITAL

WELCOME

Welcome to the RGIT Newsletter. We plan to issue a newsletter every 6 months providing updates on the following:

- Standard Operating Procedures (SOPs)
- Internal Staff updates
- Training Events
- Website Updates
- New/Updated Guidelines
- Regulatory Updates

If there are any topics you would like to see covered, please let us know.

CONTACT UPDATES

RGIT have been informed not to contact Chantel for insurance related emails, but instead; send all enquires to the generic email address insurance@imperial.ac.uk



New Staff !

RGIT Welcomed 2 New Staff members into the Team:

Research Integrity Officer: **Kadambari Rai** <mailto:k.raii21@imperial.ac.uk>

Ethics and Research Governance Coordinator **Phumzile Tshuma** <mailto:p.tshuma@imperial.ac.uk>

Note: Elizabeth and Nooreen are now both on maternity leave!

SOP UPDATE

There have been changes made to the following SOPs, to include the process of submission via Combined Ways of Working (CWOW) IRAS System:

- RGIT_SOP_006 – Amendment
- RGIT_SOP_008 – CTA MHRA
- RGIT_SOP_009 – AHSC Approval
- RGIT_SOP_028 – End of Study Notification
- RGIT_SOP_035 – Development Safety Update Report
- RGIT_SOP_037 – Deviations, Violations and USM

IRAS CWOW for all CTIMP studies is now mandatory for all submissions. CTIMP studies radiation assurance will be mandatory, more information on this can be found in [HRA NHS - Step by step guide to using IRAS for combined review](#) link.

MORE INFORMATION ON

Currently CWOW has the functionality to submit amendments, DSURs, EoS and USMs. Eventually it will be used for CCC across all sites with access to documentation. The RGIT team involved in sponsorship review are encouraged to register as Organisation representatives so they can get a feel for the system, although currently only the CTIMP team are reviewing and accepting sponsor requests.

For more information can be found on [My Research Project - CWOW](#).

HRA TRANSPARENCY GUIDE

HRA transparency guidance has been updated, which includes a new way of reporting the final study report [Final Report to the REC](#), once the REC has been notified that the study has ended, the last step is to complete and submit the Final report.

COMMON QA AUDIT FINDINGS

The Quality Assurance auditing team have highlighted a few common audit findings to help decrease the chances of repetition.

1

CCC approval – Many studies are beginning without having the Capacity and Capability Confirmation (CCC) approval in place. Please ensure that you have received CCC approval before commencing any study activities. For more information, please refer to the Sponsorship Approval email (RGIT_TEMP_057 – Sponsorship and Insurance Approval email).

2

Trial Master File (TMF) – A few studies have not created a filing system i.e. electronic or hardcopy to file any documents pertaining to the study. If you would like more information on what to include in the TMF please refer to RGIT_SOP_005 – TMF Guidance.

3

Communication – When waiting for Sponsorship approval and greenlight, please ensure that you are maintaining good communication between members of the research team and the divisional research team (DRM); to ensure everything is in place including CCC Approval.

INFORMATION TECHNOLOGY (IT) TIP

If you want to ensure that you are sending the correct recipient an email and would also like to help prevent sending errors or Data Protection breach, it is advised that you could add a photo to your Imperial Email account, that way you can easily identify your recipient.



On Behalf of Everyone from the Research Governance and Integrity Office, we would like to wish you all a Happy Christmas and a Wonderful New Year !

We welcome your suggestions for topics to be displayed in this, if you have any suggestions please send an email to [Rosemary Ichaba](#)