NEWSLETTER

ISSUE NO 08 | Jan 2025

(issued every 6 months)

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

Staff Updates

Keith Boland has left the RGIT and Eleanor Izzard has joined the RGIT training team (Becky Ward's) on Nov 25th as a Research Regulatory Facilitator (RRF).

Quality Management System Updates

Title	Doc Reference Number	Version Number	Date
AHSC Approval	RGIT_SOP_009	14.0	04-Jun-24
Audit	RGIT_SOP_018	11.0	14-Jun-24
Maintaining Training Records	RGIT_SOP_024	9.0	14-Jun-24
Development Safety Update Report	RGIT_SOP_035	9.0	14-Jun-24
HRA Approval	RGIT_SOP_039	6.0	14-Jun-24
ICREC-SETREC Safety Reporting	RGIT_SOP_045	5.0	14-Jun-24
ICREC-SETREC Ethics Application Process	RGIT_SOP_044	6.0	26-Jun-24
Honorary Research Passport	RGIT_SOP_034	7.0	02-Jul-24
IMP Management	RGIT_SOP_026	10.0	02-Aug-24
NIGB Application (CAG)	RGIT_SOP_017	12.0	06-Aug-24

Computerised Systems	RGIT_SOP_030	9.0	29-Aug-24
ICHT Trust Approval No REC	RGIT_SOP_038	6.0	29-Aug-24
TMF Guidance	RGIT_SOP_005	11.0	12-Nov-24
E-TMF Management	RGIT_SOP_051	1.0	12-Nov-24
Research Fraud and Misconduct	RGIT_SOP_036	6.0	18-Nov-24
Applying for NHS REC Approval	RGIT_SOP_003	11.0	19-Nov-24
Medical Device Monitoring	RGIT_SOP_014	11.0	19-Nov-24
ICHT Amendment Approval (non-CSP)	RGIT_SOP_032	8.0	25-Nov-24
Database Lock	RGIT_SOP_046	3.0	26-Nov-24
Public Databases	RGIT_SOP_022	13.0	02-Dec-24
Electronic Signature Set-Up	RGIT_SOP_043	4.0	02-Dec-24
Medical Device Safety Reporting	RGIT_SOP_050	3.0	02-Dec-24
ICHT Trust Approval	RGIT_SOP_031	10.0	04-Dec-24
OID Contracts Flowchart (App.5)	RGIT_TEMP_024	6.0	06-Jun-24
Template CV	RGIT_TEMP_038	3.0	14-Jun-24
Development Safety Update Report (DSUR) Template	RGIT_TEMP_049	2.0	14-Jun-24
ICREC Participant Information Sheet	RGIT_TEMP_077	3.0	14-Jun-24
SETREC Participant Information Sheet	RGIT_TEMP_078	3.0	14-Jun-24
ICREC Consent Form	RGIT_TEMP_079	2.0	14-Jun-24
SETREC Consent Form	RGIT_TEMP_080	2.0	14-Jun-24
Study Delegation Log	RGIT_TEMP_039	3.0	02-Aug-24
Subject Dispensing and Return Accountability Log	RGIT_TEMP_040	3.0	02-Aug-24
Drug Accountability Log	RGIT_TEMP_041	3.0	02-Aug-24
IMP Destruction Log	RGIT_TEMP_042	3.0	02-Aug-24
Template ICF for Adults with Capacity	RGIT_TEMP_034	7.0	18-Sep-24
Sponsorship and Insurance Registration Form	RGIT_TEMP_023	18.0	19-Sep-24
Sponsorship and Insurance Approval email	RGIT_TEMP_059	12.0	07-Oct-24
IRAS Content Index - Integrated Dataset	RGIT_TEMP_010	3.0	21-Nov-24
RGIT & Site Contact Details	RGIT_TEMP_014	4.0	25-Nov-24
Template Protocol for non-CTIMPs - Qualitative Research	RGIT_TEMP_027_b	1.0	28-Nov-24
Guide to Writing a Participant Information Sheet	RGIT_TEMP_033	8.0	28-Nov-24
Study Audit Tool Template	RGIT_TEMP_052	6.0	28-Nov-24
Audit Plan	RGIT_TEMP_069	3.0	28-Nov-24

Audit Report	RGIT_TEMP_070	4.0	28-Nov-24
CAPA Report	RGIT_TEMP_071	3.0	28-Nov-24
System Risk Self-Assessment Form	RGIT_TEMP_072	3.0	28-Nov-24
CTIMP Decision Committee Charter	RGIT_TEMP_083	1.0	05-Dec-24
Getting started with Worktribe - RGF	RGIT_GUID_026	5	01-Jul-24
Quick Start: RGIT Worktribe Guidance	RGIT_GUID_028	3	01-Jul-24
Quick guide Worktribe Ethics Module - Applicant	RGIT_GUID_029	4	01-Jul-24
EDGE User Guide	RGIT_GUID_033	4	28-Aug-24
EDGE User Guide for R&D Directorate & Admin users	RGIT_GUID_034	2	26-Nov-24
PRO Process map	RGIT_GUID_011	3	02-Dec-24
Getting started with Worktribe - RGF	RGIT_GUID_026	5	01-Jul-24

Additional Updates

3yr SOP Review

The RGIT 3 yearly SOP review has now drawn to a close.

Trial Registration

All new CTAs (clinical trial applications) of CTIMPs with at least a site in Europe are now submitted by using CTIS (together with an associated ISRCTN and/or CT.gov application). After February 2025, the use of the EudraCT registry will be limited to some of the existing EudraCT trials, third country trials and international PIP trials.

Recent Updates

Regulatory Updates

HRA

The removal of the requirement to submit annual progress reports has been effective since Thursday 1 August 2024. Annual reviews still need to be submitted to the Confidentiality Advisory Group (CAG) through IRAS. Fatal and life-threatening SUSARS still need to be reported to the MHRA and the REC immediately. For CTIMPs from combined reviews, SUSARS and safety reports need to be submitted to the MHRA who, if action is required, will instruct to submit a substantial amendment to the REC. Other SUSARS or annual safety reports will need to be submitted to the REC, and the reply email by the REC will act as the acknowledgement of receipt.

The Organisation Information Document (OID) template for non-commercial research in the NHS/HSC has been also updated, and the most recent version is dated April 2024.

Separate information about public involvement should be submitted together with Confidentiality Advisory Group (CAG) applications[1] to the REC.

[1] Please remember that 'as of 18 January 2024, applicants seeking Section 251 support for the use of confidential patient data without consent will be expected to attend the CAG meeting at which their application is being discussed. '

Following the development of the Quality Standards & Design-Review Principles to draft information for research participants (which is mandatory as of 1 December 2023), the HRA together with the Medical Research Council (MRC) has provided an online tool for guidance on participant consent and information preparation.

Since Monday 14th October, the National Contract Value Review (NCVR) applies to more studies.

For commercial sponsors to contract out to NHS and HSC organisations work for their research studies, a new model Master Confidentiality Disclosure Agreement (mMCDA) has been published. This will enable the sharing of confidential information for multiple studies with one NHS / HSC organisation.

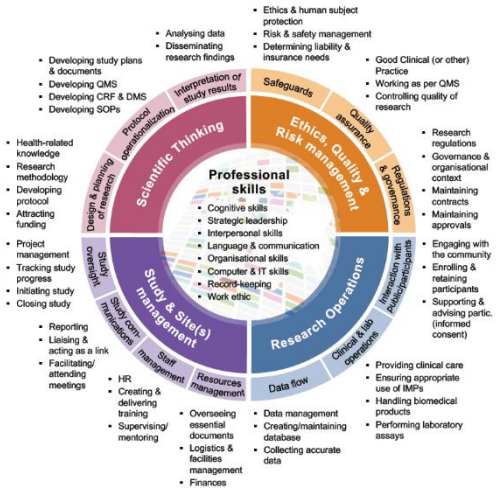
MHRA

Since the ongoing overhaul of the clinical trial regulation (October 2023), the MHRA has started notifying a risk-proportionate approach scheme for processing clinical trial authorisation (CTA)[2]. The MHRA should have put the new clinical trials regulations to parliament already, and it is likely that these will be passed in Jan 2025, with a 12-month implementation period.

Medical Devices: a new legislation will introduce 'clearer and risk-proportionate requirements that improve the safety of medical devices across Great Britain'.

Personalised Medicines: a Statutory Instrument (SI) laid in Parliament on 21st October, will provide 'a new regulatory framework meaning that medicines with a very short shelf life and highly personalised medicines can more easily be made in or near a hospital setting and can get to the patients who need them safely and much more quickly'.

WHO



On September, 25th 2024, the World Health Organization (WHO) has released a guidance 'to improve the design, conduct and oversight of clinical trials in countries of all income levels'. This should be used in harness with the WHO tool for benchmarking ethics oversight of health-related research involving human participants.

Fig. TDR Global Competency Framework for Clinical Research (WHO)

Finally, please note that he good participatory practice guidelines apply now to all clinical trials.

[2] The scheme only applies to CTA applications of lower risk clinical trials (phase 3/4), that is excluding first in human (FIH), Phase 1 or Phase 2 CTAs or related amendments.

Training Updates

GENERAL 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 ran a Research Security presentation for RGIT staff as part of a local knowledge sharing plan in November 2024.