Standard Operating Procedure for Preparing and Obtaining Approvals for Clinical Trials of Investigational Medicinal Products

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Revision Chronology:			
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JBRU/SPON/S29/01	12/03/11	To amalgamate the Guidance for Trial approvals Version 4 dated 07.07.2009 with the CTC SOP for permission and approvals for Clinical trials into an SOP for JBRU	Anne Marie Downey
JRO/SPON/S29/02	12/03/14	Add references to MHRA notification scheme, update references to GTAC, remove international procedures, clarify site specific approvals	Gemma Jones & Anne Marie Downey
JRO/SPON/S29/03	22/07/16	Integrating the HRA process and CESP systems for clinical trial applications. Decommissioning of CSP system	Nimrita Verma & Shriram Velamuri
JRO/SPON/S29/04	16/09/19	SOP Review date. Section 6.3 updated in response to HRA approval process updates. ARSAC application process updated.	Samim Patel
JRO/SPON/S29/05	08/09/22	SOP Review date. Processes updated to the reflect the new combined review submission process for MHRA, REC and HRA. Update to submission for CRN portfolio adoption and ARSAC submission also included. Title of SOP changed from: Standard Operating Procedure for Obtaining Health Research Authority Approval, Ethics Approval, Clinical Trial Authorisation and Site Approval for Clinical Trials of Investigational Medicinal Products	Nikkayla Dixon

ACRONYMS:	
ATIMP	Advanced Therapy Investigational Medicinal Product
ARSAC	Administration of Radioactive Substances Advisory Committee
CA	Competent Authority
CAG	Confidentiality Advisory Group
CESP	Common European Submission Platform
CI	Chief Investigator
COA	Compliance Oversight Advisor
CRN	Clinical Research Network
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of Investigational Medicinal Product
CTU	Clinical Trials Unit
EudraCT	European Clinical Trials Database
GCP	Good Clinical Practice
GMO	Genetically Modified Organism
GTAC	Gene Therapy Advisory Committee
HRA	Health Research Authority
HSC	Health and Social Care
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
JRO	Joint Research Office
LIP	Local Information Pack
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
NIHR	National Institute for Health Research
PI	Principal Investigator
PAF	Portfolio Application Form
PVG Manager	Pharmacovigilance Manager
QA	Quality Assurance
R&D	Research and Development
REC	Research Ethics Committee
RM(ATIMPs)	Regulatory Manager for ATIMPs
RM(P)	Regulatory Manager (Pharmaceuticals)
SI	Statutory Instrument
SOP	Standard Operating Procedure
SRA	Sponsor Regulatory Advisor
TMF	Trial Master File
UCL	University College London

SOP for Preparing and Obtaining Approvals for Clinical Trials of Investigational Medicinal Products

1. PURPOSE

This Standard Operating Procedure (SOP) describes the process for obtaining Approvals such as Health research Authority (HRA), Research Ethics Committee (REC), Competent Authority and Site Specific Approvals for Clinical Trials of Investigational Products (CTIMPs) that are sponsored by University College London (UCL) and managed within the Joint Research Office (JRO).

2. JOINT RESEARCH OFFICE POLICY

All SOPs produced by the JRO must be used in conjunction with local NHS Trust and UCL policies and procedures.

The JRO acts as the representative of the Sponsor and will be the official name used on all SOPs.

3. BACKGROUND

All SOPs are written in accordance with applicable GCP requirements as outlined in Directives 2001/20/EC and 2005/20/EC (in the UK, these Directives were transposed into UK law by SI 2004/1031, SI 2006/1928) and subsequent amendments. Where applicable it incorporates elements of “ICH GCP tripartite guidelines (E6)".

In addition, as UCL sponsors trials with EU and Northern Ireland sites, the SOPs are written to comply with EU Clinical Trials Regulation No. 536/2014.

According to The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), clinical trials of investigational medicinal products (CTIMPs) in human subjects must not start until an ethics committee has given a favourable opinion in relation to the clinical trial; and the clinical trial has been authorised by the licensing authority, prior to the start of the study.

As per the ‘Risk-adapted approaches to the management of clinical trials of investigational medicinal products’ a **Notification to the MHRA** may be made in place of a full Clinical Trial Authorisation (CTA) application. Notifications can only be made for 'Type A' trials. These are trials involving medicinal products licensed in any EU Member State if:

- they relate to the licensed range of indications, dosage and form
- or, they involve off-label use (such as in paediatrics and oncology, etc.) if this off-label use is established practice and supported by **sufficient published evidence** and/or guidelines.

A CTIMP must be reviewed by an NHS REC (or HSC REC in Northern Ireland).

The Gene Therapy Advisory Committee (GTAC) is the UK national REC for gene therapy clinical research according to regulation 14(5) of The Medicines for Human Use (Clinical Trials) Regulations 2004. If your application is for ethical approval of a gene therapy clinical trial you must apply to GTAC. However other applications that involve cell therapy and/or that are submitted to the MHRA Clinical Trials Expert Advisory Group must also be submitted to GTAC.

All research that involves NHS patients or resources must gain HRA approval (or Health and Care Research Wales (HCRW) Approval in Wales). HRA & HCRW Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC) so that you only need to submit one application. HRA and HCRW approval for England and Wales is an aligned process.

Depending on the type of trial, approval from other bodies may also be required such as

- Ministry of Justice (National Offender Management Service)
- NHS / HSC research offices
- Confidentiality Advisory Group (CAG)
- Social Care Research Ethics Committee
- Trials with genetically modified organisms: Health and Safety Executive (Contained use of genetically modified organisms (GMOs)
- Deliberate release activities: Department for Environment, Food and Rural Affairs (Defra)
- Radioactive substances: ARSAC (Administration of Radioactive Substances Advisory Committee).
  ARSAC approval will be required if the research protocol requires the administration of radioactive substances or specifies the frequency, activity or processing for an administration that would otherwise be considered standard care.

The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social care / community care research in the UK including clinical trials. It enables researchers to enter information about their project once instead of duplicating information in separate application forms. It applies filters to ensure that the data collected and collated is appropriate to the type of trial, and consequently the permissions and approvals required.

4. SCOPE OF THIS SOP

All clinical trials sponsored by UCL requiring CTA approval and managed by the JRO.

This SOP outlines the procedure for obtaining REC, HRA, ARSAC, CA and Site-specific approvals in the UK.

Where another unit (e.g. Clinical Trial Unit (CTU) / Contract Research Organisation (CRO)) is delegated to manage the trial, the specific roles and responsibilities will be outlined in an agreement between the parties. Applicable parts of this SOP will apply if it is agreed that the JRO is responsible for oversight of REC, HRA, ARSAC, CA or site-specific approval processes.

This SOP applies to the trial with sites in England and Wales. The process for approval in England and Wales is aligned (where HRA is referred to in this SOP this includes HCRW if the trial includes sites in Wales). Studies with sites in Northern Ireland or Scotland are supported through existing UK-wide compatibility systems where each country accepts relevant centralised assurances from national coordinating functions to avoid duplication. Guidance is available on IRAS.

If your project is led from Northern Ireland or Scotland and involves NHS/HSC sites then you will not apply to the HRA. You should apply through the appropriate NHS/HSC permission process for that lead nation.

Obtaining approvals for non-UK sites may be delegated in an agreement to appropriate organisations (e.g. CTU/CRO) that the JRO has assessed as suitable for the management of non-UK sites.

The procedures for obtaining other types of approvals; not involving the HRA and CA fall outside the scope of this SOP.

5. RESPONSIBLE PERSONNEL

The Sponsor Regulatory Advisor (SRA) / Regulatory Manager for Advanced Therapy Investigational Medicinal Products (RM (ATIMPs)) together with the Chief Investigator (CI) are responsible for ensuring that appropriate ethical and regulatory approvals are obtained prior to initiating a trial.

The CI is responsible for drafting the relevant applications.
The SRA/ RM (ATIMPs), Regulatory Manager for Pharmaceuticals (RM(P)) and the Pharmacovigilance (PVG) Manager are responsible for the review and approval of the contents of the applications.
The CI is responsible for submitting the documents to HRA, MHRA and REC.

6. PROCEDURE

6.1 Applying for a EudraCT number

Clinical Trials involving an IMP (CTIMPs) must be registered on the EudraCT Database via their website: https://eudract.ema.europa.eu/eudract-web/

A copy of the email of the EudraCT number confirmation should be forwarded to the SRA/ RM (ATIMPS) for the CTA application if registered by the CI. A copy should also be filed in the TMF and Sponsor File.

6.2 Key Stages

The Three key stages of setting up a clinical research trial are:

1. Ethical, Regulatory, HRA and NIHR CRN Portfolio Submissions
2. Other Submissions
3. Site Setup

This process may also be applicable for trials where UCL is the Legal Representative.

6.3 Stage 1: Ethics, Regulatory, HRA and NIHR CRN Portfolio Submissions

A. MHRA, REC, HRA Submission and approvals & NIHR CRN Portfolio Submission

	Procedure	Responsibility
6.3.1	**IRAS Application Form** Complete the Combined Review IRAS form (this IRAS form is a combined MHRA, REC and HRA application form). Step by step instructions are available on the HRA website. Add SRA/ RM (ATIMPs) and RM(P) as collaborators on the IRAS form. Add 'UCL JRO – CTIMPs' Team as 'Sponsor or Sponsor Delegate Organisation'.	CI

	Procedure	Responsibility
6.3.2	**Associated Documents** Send the **PIS and ICF Template** (associated templates), along with the **Pregnancy Monitoring Information Sheet Template** and **Pregnancy Monitoring ICF Template** (associated templates) (if applicable) to the CI for drafting for the trial.	SRA/RM (ATIMPs)
	Send all generic documents specified in the combined checklist of the IRAS application form to the SRA/ RM(ATIMPs) for review and inform them when the IRAS form is ready for review. NB: All patient specific documents (Information Sheet, Consent form, GP Letters, Diary Cards etc) must have the IRAS ID on them.	CI
6.3.3	**Application Review** The SRA/ RM(ATIMPS) will review the IRAS form and supporting documents (including cover letter) and will provide comments. All review comments/correspondence should be filed in the Sponsor File. The Medicines Information section is reviewed by the Regulatory Manager-Pharmaceuticals. *Sections 6.3.1 - 6.3.3 may be repeated until final versions are agreed between the CI, the SRA/ RM (ATIMPS) and RM(P).*	SRA/ RM (ATIMPs) / RM(P)
6.3.4	**MHRA Supporting Documents** CTA applications and notifications to the MHRA require submission of specific supporting documentation alongside a completed application form as per the MHRA website. Prepare/obtain the required supporting documents including a **CTA Application Cover Letter** (associated template) in liaison with the SRA/RM (ATIMPs), RM(P) and PVG Manager. Selected supporting documents will be identified as per Sponsor's SOP S24 (Standard Operating Procedure for Sourcing Investigational Medicinal Product for UCL Sponsored Trial). The IMP label template will be prepared as per the Sponsor's SOP 09 IMP labelling The Investigator's Brochure will be prepared as per the Sponsor's SOP 03 for creating and maintaining an IB where applicable Forward all supporting documents to the SRA/ RM (ATIMPs) for review and approval. The proposed Reference Safety Information (RSI) document for the trial is reviewed by the PVG Manager.	CI SRA/RM (ATIMPs)/ RM(P)/ PVG Manager
6.3.5	**Pharmacy Assurance Approval (pre-submission review)** For multisite trials (Phase I-III only) ensure that the following documents are submitted for Pharmacy Assurance no later than	SRA/RM (ATMPs)

	Procedure	Responsibility
	three weeks prior to submission for HRA and HCRW Approval. • either the draft Integrated Research Application System (IRAS) Form or selected information from the form in a covering email (details on HRA website) • protocol • investigator's brochure(s) • summary of product characteristics • investigational medicinal product (IMP) labels as sent to the Medicines and Healthcare products Regulatory Authority (MHRA) • pharmacy manual (recommended) • material safety data sheet(s) (recommended) Where appropriate the JRO RM(P)s who are registered as approved Pharmacy Assurance Reviewers with the HRA should be selected for conducting Pharmacy/technical assurance review via the 'self-managed study review' route. For single site studies Pharmacy Assurance is not required as the local pharmacy will conduct a review as part of their feasibility process.	
6.3.6	**Radiology Review** Studies involving ionising radiation or radioactive substances are required to undergo a radiation review. This review can be done via two routes: HRA Radiation Assurance or Self- managed review. The Ionising radiation sections of IRAS to be completed should be generated through the original IRAS system following instructions detailed on: https://www.myresearchproject.org.uk/help/hlpcombinedreview.aspx Self-managed reviews For trials in which a CRE/MPE has already been identified from a partner hospital (i.e. UCLH, Royal Free), the completed Ionising radiation form along with the protocol and Participant Information Sheet (PIS) should be submitted to both the CRE/MPE reviewers and the Radiation Assurance: radiation.assurance@hra.nhs.uk To initiate radiology review at UCLH the documents should be submitted to: uclh.imagingreviews@nhs.net HRA-managed reviews For trials in which an appropriate CRE or MPE reviewer has not been identified from a partner hospital, the HRA-managed route	CI / SRA/RM (ATMPs)

	Procedure	Responsibility
	can be used. The completed Ionising radiation form along with the protocol and Participant Information Sheet (PIS) should be submitted to HRA Radiation Assurance: radiation.assurance@hra.nhs.uk following guidance: https://www.myresearchproject.org.uk/help/hlpradiationassurance.aspx#How-to-Apply	
6.3.7	Finalise the combined review IRAS application form and upload all supporting documents listed on the project documents checklist.	CI
6.3.8	In the project dashboard of IRAS 'Check your answers' and 'Identify missing information'. Address any outstanding validation checks until no banner is shown. Once 'Content verified' is displayed in IRAS send the application through for **Sponsor authorisation** by clicking 'Request Review'.	CI
6.3.9	Confirm **Sponsor authorisation** of the finalised IRAS form by checking the 'I confirm this submission' followed by the 'submit' button.	SRA/RM (ATIMPs)
6.3.10	CI books REC meeting through the online booking service. Once REC meeting has been booked, submit application at the end of the booking confirmation page. (For further guidance on the Online Booking Service refer to the HRA website)	CI
6.3.11	CI to file a signed copy of the IRAS form and supporting documents in the TMF and forward copies to the SRA/ RM (ATIMPs) for filing in the Sponsor File.	CI / SRA/RM (ATIMPs)
6.3.12	**NIHR Portfolio Application** Applications for adoption onto the NIHR portfolio are made through the Non-commercial Portfolio Application service. You must have an account with CPMS to submit an application. A copy of the protocol and evidence of the research funding secured must be submitted with the application. Applications should be made as soon as funding has been secured prior to regulatory MHRA, REC & HRA submission.	CI
6.3.13	**HRA Assessment, REC Review and MHRA Assessment** HRA issues outcome of the Initial Assessment via letter to CI. CI to forward the HRA Initial Assessment Letter to Sponsor. REC issues Validation Letter confirming application valid. CI to forward this letter to Sponsor. MHRA issues acknowledgment of a valid application.	CI
6.3.14	The CI should attend the REC meeting at which the relevant REC	CI / SRA/RM

	Procedure	**Responsibility**
	will consider their application. The application will be assessed and discussed at the REC meeting and the applicant will be sent a letter informing them of: • Favourable opinion with standard conditions • Favourable opinion with standard and additional conditions • Provisional opinion with request for further information, clarification, or revision • Provisional opinion pending consultation with a referee – a written request for information may be made following receipt of the referee's advice • Unfavourable opinion Assessment, response and timelines are set out in the REC SOPs. CI to inform the SRA/RM (ATIMPs) of the opinion. CI to address all the conditions and remarks ***in liaison with the SRA/ RM (ATIMPs)*** and submit response to the REC for final opinion. Ensure all documentation submitted to the REC and all correspondence received from the REC are forwarded to the SRA/ RM (ATIMPs) for filing in the Sponsor File. CI to file copies of these documents in the TMF.	(ATIMPs)
6.3.15	When the CTA application has been assessed by the MHRA the applicant will be sent a letter informing them of: • Acceptance of the request for a clinical trial authorisation OR • Acceptance of the request for a clinical trial authorisation subject to conditions, OR • Grounds for non-acceptance of the request for a clinical trial authorisation. Forward the response letter to the CI once received. MHRA will send a copy of this letter to the HRA. If conditions or remarks are listed, address all the conditions and remarks ***in liaison with the CI and RM(P) / PVG Manager*** and submit an amended request to the MHRA. An amended request for a clinical trial authorisation to the MHRA must be made within the timelines set out in SI 2004 1031, unless otherwise agreed with the MHRA. On receipt forward the Acceptance/ Grounds for non-acceptance of the request to the CI and retain a copy for the Sponsor file. Ensure that all conditions/remarks on the CTA letter are addressed and **all related documentation to evidence that conditions/ remarks have been met retained in the TMF and Sponsor File**.	CI / SRA/RM (ATIMPs)
6.3.16	<u>HRA Final Approval</u> HRA will issue Letter of HRA Approval, once REC & MHRA	CI

	Procedure	Responsibility
	approvals are in place. CI to file copy of this document in the TMF. CI to forward the HRA Approval Letter to the Sponsor for filing in the Sponsor File.	
6.3.17	**Withdrawals** Unexpected events or additional information may require the JRO to withdraw a request for authorisation before the MHRA has reached its decision on authorisation. The SRA/RM (ATIMPs) should withdraw the application by selecting the 'withdraw' button within IRAS. An application can be withdrawn any point up until the project is approved.	SRA/ RM (ATIMPs)

6.4 Stage 2: Other Submissions (Gene therapy, ARSAC)

GTAC

For Gene therapy and other approvals, follow the usual procedure of submissions in IRAS. If your application is for REC approval for a gene therapy or cell therapy trial you must apply to the Gene Therapy Advisory Committee.

Preliminary Research Application (PRA)

For research involving administration of radioactive materials, a Preliminary Research Application (PRA) must be completed in IRAS and submitted to the Administration of Radioactive Substance Advisory Committee (ARSAC).

	Procedure	Responsibility
i	Complete the Preliminary Research Assessment (PRA) form in original IRAS. Note: This form is generated by the responses in the project filter page and it is listed in the Project Forms list in the Navigation Page view in IRAS.	CI
ii	Check the completed PRA form and confirm it can be electronically authorised by the lead Clinical Radiation Expert and/or lead Medical Physics Expert	SRA/RM (ATIMPs)
iii	Check form has been electronically signed by the lead Clinical Radiation Expert and/or lead Medical Physics Expert and electronically authorise Sponsor Declaration of PRA form	SRA/RM (ATIMPs)

	Procedure	Responsibility
iv	Submit the signed PRA form to ARSAC via the ARSAC online portal with a copy of the Participant Information Sheet (PIS) at the same time as the REC application has been submitted. If the trial has gone through radiation assurance, also attach F1 of the research exposure form. Note: The protocol should also be submitted for trials involving therapeutic nuclear medicine procedures.	CI / SRA/RM (ATIMPs)
v	ARSAC will send all communication regarding the application via the ARSAC online portal. All responses should be sent via the portal.	CI/ SRA/ RM (ATIMPs)
vi	ARSAC will send a reference number and the required fee depending on the type of study for payment. Payment will need to be received before ARSAC issue a final decision.	CI
vii	Once ARSAC has approved the trial, they will upload the approval letter to the portal. This letter should be downloaded and provided to the HRA and participating sites.	CI/ SRA/ RM (ATIMPs)

NB: HRA will not issue HRA approval for the study, until ARSAC approves the study.

6.5 Stage 3: Site Setup

NHS Sites in England & Wales

The CI to send the Initial assessment letter from HRA along with local Information pack to the site R&D department who will confirm the sites' capacity and capability. (Follow the pathway in Appendix 1)

	Procedure	Responsibility
6.5.1	Upon receiving the Initial Assessment letter, CI to email Local Information Pack (LIP)* and the HRA Initial assessment letter to the site R&D and PI team. *Refer to IRAS guidance for essential documents to be included in the Local Information Pack	CI
6.5.2	Send the Final HRA approval letter and updated LIP (if applicable) to the site R&D and PI team.	CI
6.5.3	Site R&D to provide confirmation of capacity and capability for conducting the trial at the site.	Site R&D
6.5.4	Contract signed off (fully executed site agreements in place). Note: Some sites will not issue confirmation of capacity & capability until the fully executed site agreement is in place.	SRA/RM (ATIMPs) / Site R&D
6.5.5	Schedule a Site Initiation Visit (SIV) and proceed with Site activation process as per SOP JRO/SPON/S20. Note: SIV should only be scheduled with the site once all trial set-up procedures have been completed as per SOP JRO/SPON/S16.	SRA/RM (ATIMPs)

For NHS Sites in Scotland & Northern Ireland

Studies with sites in Northern Ireland or Scotland are supported through existing UK-wide compatibility systems where each country accepts relevant centralised assurances from national coordinating functions to avoid duplication. Guidance is available on IRAS.
HRA shares applications information with appropriate review boards in Scotland and Northern Ireland.

Refer to the HRA website or IRAS Help section for approvals for NHS/HSC sites in Scotland and Northern Ireland.

	Procedure	Responsibility
6.5.6	Upon receiving the Initial Assessment letter, CI to email Local Information Pack (LIP)* and the HRA Initial assessment letter to the site R&D and PI team. *Refer to IRAS guidance for essential documents to be included in the Local Information Pack.	CI
6.5.7	Local governance checks.	Site R&D
6.5.8	Send the Final HRA approval and updated LIP (if applicable) to the site R&D team and PI team.	CI
6.5.9	Site R&D Approval issued.	Site R&D
6.5.10	Contract Signatures. Note: Some sites will not issue R&D Approval until the fully executed site agreement is in place.	SRA/RM (ATIMPs) / Site R&D

Non-NHS sites (e.g. University, Private practice, Phase 1 Unit)

HRA approval does not cover non-NHS sites. For these sites the non-NHS/HSC Site Assessment Form (available in IRAS) should be provided with the REC application and the suitability of the site will be included as part of the ethical review.

Site Assessment Form(s) will be submitted to the REC responsible for reviewing the trial as a whole. The CI in liaison with the local PI (where applicable) will be responsible for the application.

The outcome of the Site Assessment Form application will be included in the notification of ethical opinion given by the REC.

	Procedure	Responsibility
6.5.11	List the non-NHS sites in Part C of the IRAS application form for ethical review.	CI
6.5.12	Complete a non-NHS/HSC Site Assessment Form for each non-NHS/HSC site.	CI

6.5.13	Upload electronically the signed Site Assessment Form to the REC Form Checklist Tab. Upload a copy of the following documents as well: • A short CV for the Principal Investigator(s) • Evidence of insurance or indemnity (not required for Phase 1 trials in healthy volunteers where the site is accredited by the MHRA) • Local versions of documentation if they are significantly different to the main version	CI
6.5.14	Submit REC Application Form	CI

7. REFERENCES

The Medicines for Human Use (Clinical Trials) Regulations 2004
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
http://www.legislation.gov.uk/uksi/2006/1928/made

The Clinical Trials Directive (2001/20/EC)
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2005_28/dir_2005_28_en.pdf

Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of a substantial amendment and declaration of the end of the trial, Revision 3 March 2010
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2010_c82_01/2010_c82_01_en.pdf

JRO SOPS and Working document templates:
https://www.ucl.ac.uk/joint-research-office/sops-and-templates

Health Research Authority (HRA)
http://www.hra.nhs.uk/

ARSAC Application
https://www.gov.uk/guidance/how-and-when-to-submit-research-applications-to-arsac

NIHR CRN Portfolio Adoption
https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/crn-portfolio.htm

Resources

For guidance on using IRAS combined review, refer to the following link on the HRA website:

Step by step guide to using IRAS for combined review:
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/step-step-guide-using-iras-combined-ways-working-cwow/#sponsor

For additional information on completing REC applications, go to:
https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/

For additional information on completing applications to the MHRA, go to:
http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Applyingforaclinicaltrialauthorisation/index.htm

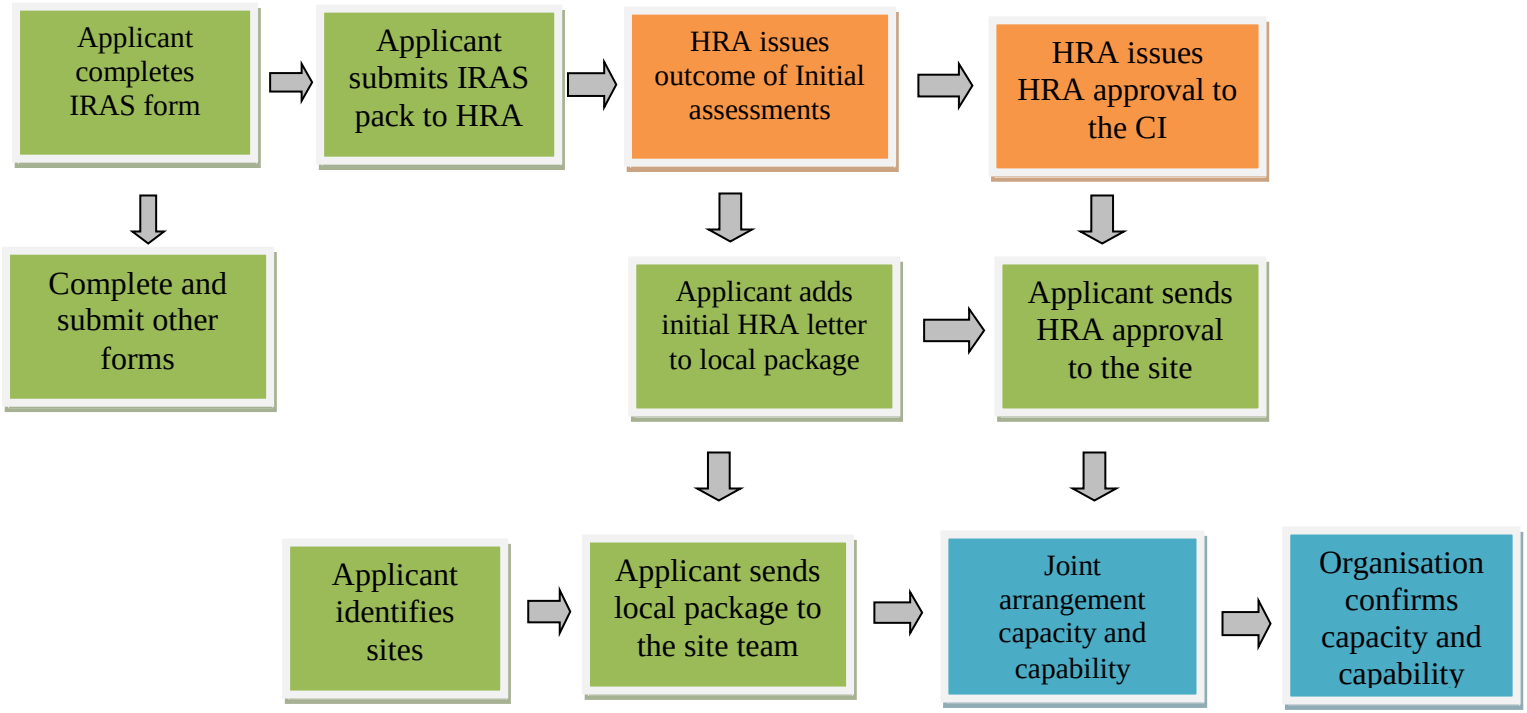
Review timelines:

https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/

https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

8. APPENDICES

Appendix 1: Overall HRA approval pathway



9. TEMPLATES/LOGS & SOPS ASSOCIATED TO THIS SOP

1	JRO SPON S07 Standard Operating Procedure for granting UCL sponsorship for Clinical Trials of Investigational Medicinal Products (CTIMPs)
2	JRO_SPON S09: Standard Operating Procedure for Investigational Medicinal Product Labelling
3	JRO SPON S28: Standard Operating Procedure for Ensuring Appropriate Insurance Provision for UCL Sponsored Clinical Trials and Clinical Research Studies Managed by the JRO or UCL CTUs
4	JRO SPON SOP S03: Standard Operating Procedure for Creating and Maintaining an Investigator's Brochure (IB) for UCL Sponsored CTIMPs
5	JRO SPON SOP S24: Standard Operating Procedure for Sourcing and Supply of Investigational Medicinal Products for UCL Sponsored Trials managed by JRO
6	JRO SPON S20: Standard Operating Procedure for Initiation of a CTIMP
7	JRO SPON S16: Standard Operating Procedure for Set-up of JRO managed UCL Sponsored CTIMPs
8	Process overview on setting up CTIMP with UCL JRO
9	CTA and REC Application Cover Letter Template
10	JRO SPON S08: Standard Operating Procedure for Contracting in UCL Sponsored Clinical Trials
11	JRO SPON 09: Standard Operating Procedure for Investigational Medicinal Product Labelling
12	PIS and ICF template
13	Pregnancy Monitoring Information Sheet Template (Partner)
14	Pregnancy Monitoring ICF Template (Partner)

10. SOP DISSEMINATION AND TRAINING

SOPs relevant to the JRO only, will be distributed to the concerned JRO staff, by the named author/delegate under section 11.0 of the SOP. Staff involved by the SOP will sign the SOP training log (Section 12. SOP TRAINING LOG) which is part of each SOP.
The training will constitute of the person reading the SOP and asking specific questions to the author of the SOP.

SOPs relevant to "JRO staff and investigators" will be provided to the investigators during trial set-up where applicable and at the time of the trial initiation.

11. SIGNATURE PAGE

Author and Job Title:	Nikkayla Dixon, Sponsor Regulatory Advisor
Signature:	DocuSigned by: Nikkayla Dixon EF2DE1E12340484...
Date:	08 August 2022 | 09:21 BST
Authorised by: Name and Job Title	Helen Cadiou, Head of QA
Signature:	DocuSigned by: Helen Cadiou 9FE319AE9B744D5...
Date:	08 August 2022 | 09:49 BST

12. SOP TRAINING LOG

	Name of Staff (Capital letters)	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
1							
2							
3							
4							
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	Name of Staff (Capital letters)	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
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	Name of Staff (Capital letters)	**Job Title: Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
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	Name of Staff (Capital letters)	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
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