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Joint Research Compliance Office (JRCO)

JRCO

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Overview

- JRCO Remit
- Interactions
- Example Approval Process
- HRA Developments

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JRCO Remit

The Joint Research Compliance Office exists to help the AHSC and its researchers meet the requirements of research governance, ensuring Imperial fulfils the legal, ethical and scientific obligations of the healthcare research process.

This is accomplished by using a variety of Standard Operating Procedures that relate to multiple aspects of research management and approval requirements. These can be accessed at:

http://www.imperial.ac.uk/joint-research-compliance-office/standard-operating-procedures/

The JRCO has a dedicated team overseeing research activity across the AHSC. Contacts can be accessed at:

http://www.imperial.ac.uk/joint-research-compliance-office/about-us/staff-list/

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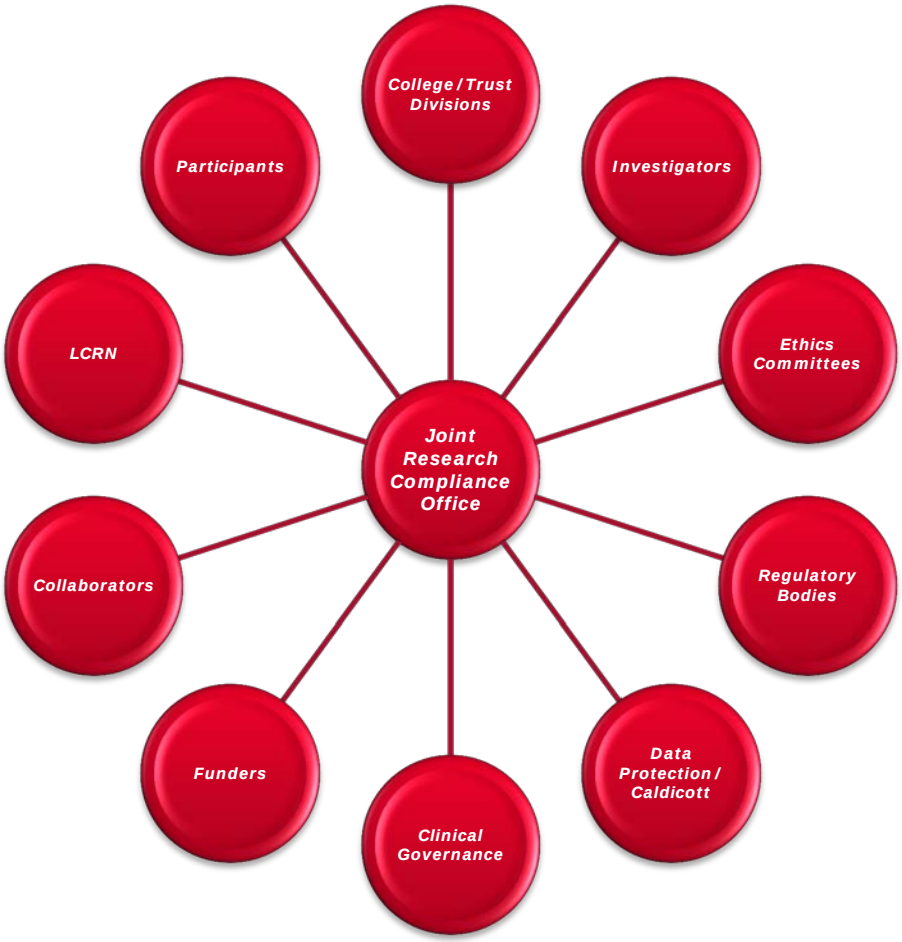
JRCO Interactions



- JRO
- BRC
- CRF
- Support Services
- ICTU
- Tissue Bank
- ICREC

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Example Approval Process for AHSC Sponsored Research

First Contact

- Researcher submits study documents to JRCO for sponsor assessment
- JRCO checks for valid document set and commences sponsor review

Dissemination

- JRCO emails out study documents to PI, Divisions, Contracts and support services as required once initial review completed
- JRCO completes sponsor review and instructs researcher to submit for ethics/regulatory approval

Review

- Divisions complete feasibility review with support services
- Divisions return statement of activities or confirmation of feasibility approval to JRCO. Contracts confirm sign-off (if required)

Confirm

- JRCO conducts final checks and receives HRA approval confirmation
- JRCO confirms readiness to sponsor, PI, Divisions, Contracts and support services

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HRA Approval

The HRA has rolled out an approval process to consolidate ethics and approval requirements for health related research in England.

This requirement covers all health related research being submitted to the National Research Ethics Service (NRES) for review and approval

It also includes all pre existing studies where amendments are being submitted for approval.

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Process

The HRA review process is for research studies taking place in England in the NHS, and approval will be issued on behalf of the NHS. This will provide assurance to the sites, researchers, patients and sponsors that:

- the study has a favourable ethical opinion AND
- the study protocol and arrangements are compliant with relevant legal and regulatory requirements AND
- the study documents are compliant with nationally agreed standards

This is a major change to the approvals process, without the perceived ‘extra’ NHS review process that researchers and companies have struggled with. So research in England will benefit from a streamlined approvals process as well as the unique opportunities provided by the NHS.

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Process

- Single application via (IRAS) for ethics approval in parallel to HRA approval
- Medical Radiation Exposure statements to be collected prior to submission
- Single technical Pharmacy review
- Model contracts or statement of activities to be used
- Research Passport – who needs what type of access – HRA will advise
- HRA approval will be an assurance of regulatory and ethics requirements
- NHS sites will focus on capacity and capability to support the research and ensure local SOPs can meet the needs of the research protocol

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Sponsor Requirements

All non-commercially sponsored applications must be accompanied by a completed Statement of Activities, which details the activities to be undertaken locally and whether these will be undertaken by local or central study staff.

For studies where activities will differ at different host organisations (i.e. where there is more than one ‘site type’ in the study) one Statement of Activities must be provided per site type

HRA assessment will review the consistency of activities described in the Statement of Activities with the description within the protocol, participant information sheet, and other study documents

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Statement of Activities

Includes:

- Study information
- Local site requirements an information
- Schedule of events defined by protocol
- Finance details – site specific
- Material Transfer considerations and process
- List of activities to be carried out at site

This document is evolving in practice and is subject to change following feedback

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Top Level Process for Site Approval

ASSESSING	ARRANGING	CONFIRMING
Assessment of the capacity and capability of the participating organisation to deliver the study. **Endpoint: Joint decision by the Sponsor and Participating Organisation that the Organisations is selected to take part in the study AND listed on the IRAS form.**	Sponsor and participating organisation actively puts in place all the practical arrangements to ensure it has the capacity and capability to deliver the study. A study delivery timetable is agreed. Endpoint: All arrangements are in place. Sponsor confirms site participation. The contents of the Statement of Activities or agreement is ready to be executed and HRA approval has been granted	Participating organisation confirms that it has the capacity and capability to deliver the study by email or execution of the agreement where one is required. Endpoint: Participating organisation is ready to recruit to the study to the timetable agreed with the Sponsor.
Supporting HRA Research Support Functions – Study Specific: **1. Providing internal and external investigators wishing to undertake a specific study at the site with:** **i. Practical support around agreeing arrangements for study set-up.** **ii. Advice on study set-up and legislative requirements.** **2. Providing advice and support on research related to higher degrees to both students and supervisors.** **4. Undertaking an early assessment of operational requirements for the conduct of the study and ensuring there are proportionate systems in place to mitigate and manage any identified study risks, in order to effectively deliver the study through its life cycle.** **5. Ensuring that the NHS organisation has both the capacity and capability to undertake the study – that is, bearing in mind the inclusion and exclusion criteria and the resources required, will it be possible to recruit the required number of participants within the timescale of the study delivery period and conduct the study in accordance with the protocol? This can include discussions with the local study team, NIHR Clinical Research Network (if a portfolio study) and sponsor leading to a proposed start date.** **……** **NOTE, where CRN feasibility services are used prior to the assess stage, this aligns with:** **3. Supporting investigators to prepare and submit expressions of interest to commercial and where required non-commercial sponsors.**	Supporting HRA Research Support Functions – Study Specific: 6. Supporting investigators in putting in place the necessary practical arrangements to conduct the study protocol in line with the responsibilities agreed with the sponsor, including all required safety arrangements. 7. Ensuring that the appropriate management/supervision and oversight arrangements are in place for all aspects of the study. 9. Ensuring that the ethically approved arrangements are in place for identifying and approaching potential participants, including managing any transfers or referrals of patients. 12. Having delegated responsibility for, or working with, their Human Resources Department to operate the Research Passport Scheme to issue (in line with HRA Approval conditions) Honorary Research Contracts and Letters of Access for research staff not employed by that NHS organisation.	Supporting HRA Research Support Functions – Study Specific: 8. Executing contracts/agreements and agreeing a budget for the delivery of the study in line with HRA Approval conditions. 13. On the basis of HRA Approval, confirming that the site will participate and finalising with the sponsor a timetable for study start/study initiation and study delivery. …… NOTE, organisations are expected to supportively manage studies throughout their life cycle through-out the stages: 10. Managing the resources required to deliver the study both at study set up and throughout the study life cycle in line with HRA Approval conditions, HSG(97)32 and AcoRD guidance. 11. Ensuring the site recruits the number of participants stated in the original application (or a revised target) within the time line agreed with the sponsor. 14. Following an updated HRA Approval make the necessary arrangements to implement amendments or, very occasionally and in discussion with the sponsor, withdraw from participation in the study if the amendment adversely affects the capacity and capability of the organisation to deliver the research to the new information.

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Site Approval

- Consists of capacity and capability assessment
- Local SOP compliance checks
- No regulatory checks as these reside with sponsor and HRA
- Statement of activities or contract
- Organisational confirmation – via email to sponsor
- Confirmation can only occur once HRA approval is in place
- Sponsor responsible for communicating with sites

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Summary

HRA approval will evolve over the next year

Ethics approval will form part of HRA approval with a single application route

Governance and approvals processes are very involved and take time so plan well ahead

Make sure you engage early with approvers and support services so your research is not delayed.

Any Questions?