GREAT ORMOND STREET INSTITUTE OF CHILD HEALTH

Great Ormond Street Hospital for Children NHS Foundation Trust

DIVISION OF RESEARCH AND INNOVATION

Joint Research and Development Office

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	Name	Position
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1. Scope

This SOP sets out the procedure for assessing research studies for host site R&D approval/confirmation of capacity and capability where they involve the use of patients, facilities, staff and data governed by Great Ormond Street Hospital (GOSH) and/or UCL-Institute of Child Health (ICH). This document has been written to be relevant for clinical, non-clinical and basic science research approvals. It is as relevant for reviewing those studies which are led by GOSH/ UCL- ICH researchers as well as studies that are only hosted at GOSH and led by a researcher from another organisation. **It does not apply to the review and approval of clinical audit, service evaluations, Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs). The HRA online decision tools can be used and/or the HRA contacted directly (hra.queries@nhs.net) to clarify further whether a project falls under the remit of research. Contact details of the relevant teams dealing with these types of projects can be found in the flowchart in appendix 1.**

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The activity involving patients, service users or the public in the design, management, conduct or dissemination of research should not be managed as though it is research in its own right. Information on arrangements and controls relating to public involvement is available from INVOLVE at www.invo.org.uk or the Patient and Public Involvement Research Lead (research.ppi@gosh.nhs.uk).

The legal basis for this Operating Procedure is the UK Policy Framework for Health and Social Care Research V3.3 07/11/17, Medicines for Human Use Act (Clinical Trials) 2006 and any other laws or guidelines which are relevant including the Human Rights Act 1998, Data Protection Act 2018, Freedom of Information Act 2000, Human Tissue Act 2004 and the World Medical Association Declaration of Helsinki and the International Conference for Harmonisation- Good Clinical Practice (ICH-GCP).

2. Purpose

The purpose of this document is to guide R&D staff on issuing NHS permission for those staff conducting reviews of studies which are led by GOSH/ UCL- ICH researchers as well as studies that are only hosted at GOSH and led by a researcher from another organisation.

3. Definitions

Research that falls into the scope of the UK Policy Framework for Health and Social Care Research V3.3 07/11/17 is started only if a research ethics committee and any other relevant approval body have favourably reviewed the research proposal or protocol and related information, where their review is expected or required.

4. Responsibilities

The overall responsibility for providing R&D approval/confirmation of capacity and capability lies with the GOSH Chief Executive or Director of ICH delegated to the Director of Research and Innovation (R&I), ICH Institute Manager, the Deputy Director of R&I and Head of Governance, Clinical Trials and contracts within the Division of R&I. A risk based approach is taken to deciding who confirms capacity and capability in HRA approved studies. The details of this risk based approach are listed in Appendix 2 of this SOP.

It is the responsibility of the Sponsor/PI/Chief Investigator (CI) to submit the necessary documents, and provide the required information to the Joint R&D Office so that the Governance team can conduct a review.

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It is the responsibility of the CI (and for commercial studies, the Sponsor) to submit documentation for HRA/ethics review and if appropriate to the competent authority Medicines for Healthcare Regulatory Agency (MHRA) and where relevant the HRA Confidentiality Advisory Group (CAG), and to obtain appropriate approvals from them.

It is the responsibility of the Research Governance team within the Joint R&D Office to facilitate and conduct appropriate research review as outlined in this SOP. **The role of Research Governance Manager/Research Governance and Management Officer relies on judgement i.e. requests for documentation to review for R&D approval/confirmation of capacity and capability should be based on requirement rather than just routine following of a checklist.**

5. Procedure

R&D Approval/confirmation of capacity and capability is a core function of the Joint R&D Office. Research studies must receive appropriate but **proportionate** review prior to being granted authorisation to commence at GOSH/ ICH-UCL. It is the responsibility of the R&D governance team or the Divisional Portfolio Officer under the Clinical Research Network: North Thames (CRN North Thames) to conduct a comprehensive assessment of the project in line with national and local policies. For the Divisional Portfolio Officers their review is conducted in line with the North Thames Network policies and SOPs.

In line with a proportionate approach to reviewing research studies for R&D approval/confirmation of capacity and capability, colleagues are urged to consider carefully what associated documents should be requested from the sponsor, CI or local PI of a study. You should aim to **avoid duplication of information** and avoid requesting additional forms if your particular study does not warrant them e.g.

1. Adequate information about the conduct of the research study may already have been supplied as part of the funding application proposal for ICH laboratory based studies and so a Protocol is not required.
2. CV's may not be required from research team members to prove that they are competent at conducting activities that would normally form part of the role for which they are employed (e.g. for ICH lab staff working on ICH Laboratory based projects).

However where NHS confirmation of capacity and capability is being sought, it is good practice to keep a CV on file.

5.1 Health Research Authority (HRA) approval

HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments' Research Ethics Service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

When HRA approval for a study has been granted an access, arrange and confirm (ACC) review is required for GOSH to confirm participation in the research.

5.1.1 GOSH Finance review process

The HRA approval process incorporates the financial details and research cost attribution for non-commercial studies primarily in the *statement of activities* and *schedule of events* documents. These are applicable for multi-centre studies. Those studies which are single site and are also the sponsor (or those that the sponsor is a university and the single site is the NHS Trust linked to the sponsor through a joint R&D research office arrangement) do not require these documents to be submitted to the HRA. In GOSH/ICH sponsored multi-centre studies these documents are also not required for the GOSH site.

AcoRD is the Department of Health guidance for attributing the costs of health and social care research.

The GOSH Finance workflow for reviewing the relevant sponsorship and non-portfolio AAC documents as above is outlined in Appendix 3.

5.1.2 General Data Protection Regulation

The General Data Protection Regulation (EU) 2016/679 ("GDPR") is a regulation in EU law on data protection and privacy for all individuals within the European Union (EU) and the European Economic Area (EEA). It also addresses the export of personal data outside the

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EU and EEA areas. The GDPR aims primarily to give control to individuals over their personal data and to simplify the regulatory environment for international business by unifying the regulation within the EU. This is implemented into UK law as the Data Protection Act 2018.

As per the HRA guidance if the research study involves the collection and use of personal data then additional transparency information is required to be added to participant documentation, more guidance can be found here https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/.

5.1.3 AAC process for non- NIHR portfolio adopted studies

The AAC process for non-NIHR portfolio adopted studies is completed by the R&D Office Governance team.

For those studies that the HRA deem that GOSH **does not need to formally confirm capacity and capability** than a pragmatic review is required (if any) which may include some elements of the review below at the Research Governance Manager/Research Management and Governance Officer discretion. These studies should be acknowledged from R&D to the sponsor without sending a 'notification of no objection'. These studies should not be marked as 'approved' on ReDA, but the status 'review, not approved' used and the database completed as per the ReDA guidance.

For those studies that GOSH **does need to formally confirm capacity and capability** then the Research Governance Manager/Research Management and Governance Officer must ensure that all relevant local authorisations (including Chief of Service approval(s)) are provided from support/ host departments by an appropriate member of GOSH or ICH staff via email confirmation. **If these authorisations have already been supplied at grant submission stage and/or CRAC approval (and no changes have been made to the research study) you should consider if it is necessary to request further authorisation. It may be more appropriate to notify the department or unit lead that the funding application that they authorised has been successful – giving them the opportunity to raise any concerns.**

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Support departments are defined as any department within the Trust outside the PI's and patients routine clinical department. The main ones will be the following (but this is not an exhaustive list):

- Radiology (including the use of the UCL research scanner)
- Pharmacy
- Pathology
- NIHR Clinical Research Facility
- Finance (as per section 5.1.1)

Additional information may be required for the AAC review (not an exhaustive list):

- Confirmation of PI/Local Collaborator
- Confirmation of the details of schedule of events/statement of activities by the PI
- Confirmation of the research team at GOSH, including their job roles. This includes confirmation of any research team members working at GOSH without appropriate contractual arrangements in place
- Confirmation of who will be taking informed consent and their expertise/training
- Confirmation of where in GOSH the research will take place and the activities involved
- Will any of the research activities impinge on service provision (e.g. clinic flow), clinical staff time or clinical resources or equipment?
- Will the research involve additional appointments or additional patients being referred to GOSH without this being recognised and is there an appropriate plan in place?
- Will the research project require additional desk space at GOSH?
- Confirmation of whether any research will be taking place at UCL Great Ormond Street Institute of Children Health
- Confirmation of proposed recruitment target at GOSH (if not in the Statement of activities)
- Confirmation of start/end date at GOSH (if not in the statement of activities)
- Obtaining localised participant documents

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Delegated authorisations for all GOSH Chiefs of Service are identified in **Appendix 4** (*This appendix should be updated on an annual basis).*

Once the AAC review is complete a 'notice of no objection' is issued for GOSH to the sponsor confirming capacity and capability, attaching the finalised 'statement of activities' document and/or signed agreement. Personnel delegated to confirming capacity and capability depending on IRAS research category is outlined in appendix 2.

Once the notice of no objection is issued the capacity and capability summary sheet is completed and uploaded to ReDA. ReDA is then updated as per the ReDA office guidance.

5.1.4 AAC process for NIHR portfolio adopted studies

The AAC process for NIHR portfolio adopted studies is completed by a Divisional Portfolio Officer CRN: North Thames, as per the North Thames policies and SOPs, and will liaise with the R&D office if necessary.

For those studies that the HRA deem that GOSH **does not need to formally confirm capacity and capability** than the network will acknowledge this to the R&D office and the process for review will be as 5.1.3.

When the AAC process has been completed the delegated R&MG personnel (as per appendix 2) will check the AAC review, ensure Chief of Service approval is in place, and confirm Trust authorisation for the study to the network. The CRN: North Thames network will then confirm capacity and capability for GOSH to the sponsor, attaching the finalised 'statement of activities' document and/or signed agreement. ReDA is then updated by the delegated R&MG personnel (as per appendix 2) as per the ReDA guidance.

5.1.5 Musketeers' Memorandum (MM) studies

The MM is a national agreement applicable to non-CTIMP rare disease projects with minimal local hospital costs. When one of the regional genetics centres, supported by their NHS Trust, develops a rare disease non-CTIMP project, the R&D team responsible for all the other regional genetics centres would sign off without a full review of protocol and the need for individual negotiations.

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The MM is now being supported by the NIHR CRN Genetics Specialty and it was decided that at GOSH a capacity and capability review will need to be completed before GOSH is able to participate in research linked to the MM.

In agreement with the CRN North Thames Network the process for review of these studies is as follows:

- When the CRN receives notification of future MM studies, these will be forwarded to the genetics team, coping in GOSH R&D.
- GOSH R&D will then register the study and initiate a pragmatic review (as per 5.1.3 **where GOSH does not need to formally confirm capacity and capability**).
- GOSH R&D will liaise with the genetics team*, which will also be discussed at the monthly CRN/genetics/R&D meeting, who will be asked to confirm if their team has the resource to take on the study.
- If confirmed then this will be notified to the CRN and GOSH R&D.
- GOSH R&D will then issue an acknowledgement as per 5.1.3 where GOSH does not need to formally confirm capacity and capability, copying in the CRN. If they do not wish to participate they will again inform the team.
- The CRN Study Support team will ensure GOSH and any other North Thames sites are on EDGE and GOSH R&D can input any additional information.

*PI needs to be confirmed and confirmation from PI and Genetics research team that they have the resources to undertake the study

5.2 R&D permission for non-HRA approved research

5.2.1 Case note reviews

Case note reviews are defined as projects utilising anonymised data from patient medical notes for use in research. As long as the Clinical Care team anonymises the data for the research/research team then this is excluded from consent and NHS ethics review. It has been agreed by the R&I board that for projects which are GOSH sponsored and **are only undertaken at GOSH** (*including those solely undertaken at GOSH who are sending anonymised data abroad*) these should be reviewed through the internal R&D process below and not submitted for HRA approval. For GOSH sponsored multicentre case note reviews HRA approval should be sought.

Please note that if it is confirmed that the data will be used for any **software development** then it would need to be confirmed with the HRA (hra.queries@nhs.net) whether HRA approval is required, regardless of the whether the project is single site or not.

As per the Health Research Authority guidance:

Research involving previously collected, non-identifiable information
Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research. This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research.

For case note reviews the Research Governance Manager/Research Management and Governance Officer should ensure the following:

- A protocol detailing sufficient information in regards to the project is submitted for review, including details of the proposed data to be collected and who will be collecting and anonymising the data for the research. A template case note review protocol can be forwarded if necessary
- Confirmation of the CI/supervisor at GOSH
- That only the clinical care team are extracting the clinical data and anonymising it for the research/research team
- That the R&D Data Protection Registration form is completed by the PI/researcher and is forwarded to the GOSH Caldicott Guardian (or Information Governance Officer in their absence) for approval. An e-mail approval should suffice
- The HRA online research tools http://www.hra-decisiontools.org.uk/research/ are completed to confirm that the project does not require NHS ethics approval

- For those projects that are sending data abroad it needs to be confirmed with the Caldicott Guardian/GOSH Information Governance team whether a data sharing agreement will be required and whether any funding is coming to GOSH

5.2.2 GOSH Digital Research Environment (DRE) studies

As part of the Research and Innovation Strategy, the Trust has procured a data store and digital research platform, called AnalytiXagility by Aridhia. The platform and other systems comprise the overall Digital Research Environment (DRE) to work alongside the new Electronic Patient Record (EPR) system. The DRE will provide a rich source of data for clinical audits and will underpin pioneering research on diagnosis and treatment of complex and rare conditions. The DRE will support recruitment to clinical trials and also enable GOSH to capitalise on future digital developments such as artificial intelligence.

- If the study solely comprises the use of the GOSH DRE for data analysis that does not involve anonymised GOSH clinical data (researcher's own data) then they can be directed to DREProjects@gosh.nhs.uk for further discussions.
- If the study involves the clinical care team extracting anonymised data from GOSH medical records as a case note review outside the DRE and then using the DRE for the data analysis then the process for a case note review needs to be followed as per section 5.2.1. The DRE team would need to be notified of the use of the DRE for this purpose at DREProjects@gosh.nhs.uk. The use of the DRE for this purpose will be covered under *17WB03 17/LO/0008 Use of routine GOSH data for research.*
- If the study involves the use of the GOSH DRE for data analysis of anonymised GOSH Clinical Data in which the DRE team extract the data for the project then this will be covered under *17WB03 17/LO/0008 Use of routine GOSH data for research.* The researcher needs to complete a GOSH DRE application form which will be reviewed and approved by the GOSH IG team (Information Governance Manager or Caldicott Guardian). If there are complex IG issues to address then this may be reviewed by the DRE RDAG (Research Data Access Group) in which approval will be obtained from them.

DREProjects@gosh.nhs.uk should be copied in to the R&D approval letter.

The study may involve other research aspects in addition to utilising the DRE therefore additional governance checks may need to be completed (i.e. IRAS form needs to be completed).

5.2.3 UCL GOS ICH research studies

The governance checklist for research studies conducted by or at UCL Great Ormond Street Institute of Child Health (including studies that may use NHS tissue or data approved for future research under an overarching REC favourable opinion letter) or other research projects not requiring HRA/NHS ethics approval is outlined in appendix 5.

5.3 Product evaluations

As with research and clinical audit, product evaluations require Trust approval before they can begin.
Product Evaluation (or 'Post Market Evaluation Study') is a study of CE marked device being used for its intended purpose and include, for example, user preference studies, patient outcome studies, studies to monitor long-term performance of a device. If the product being evaluated is not CE marked or not being used for its intended purpose it is likely to fall into the category of research. In some situations product evaluations will require ethical review.

The researcher should complete a product evaluation/post marketing study registration form and forward to R&D for review. The form submission should also include Chief of Service/Clinical Lead approval and a study proposal/protocol.

The R&D governance team should review and seek initial opinion from the HRA (hra.queries@nhs.net) in whether the product evaluation is classed as research. If the HRA provide an opinion that the study is research then the research approval process should be followed. If the HRA provide an opinion that the study is not research, the study may require approval via the GOSH Medical Supplies and Equipment Steering group (MESG). The documents should be forwarded to the MESG chair for review. The product evaluation review process is outlined in the flowchart in appendix 6.

It should be noted that appropriate agreements may be required with any third parties involved such as manufacturers.

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5.4 Studentship projects

ICH students are mainly postgraduates and will either be Post Graduate Research (PhD) or Post Graduate Taught (Masters) students. Some iBSc students at ICH also complete a research project and occasionally undergraduate students from other organisations wish to conduct research to include access to GOSH.

For all students the research project needs to be registered separately with R&D using the student registration form and linked to another project if necessary.

For Post Graduate Research students the research is usually stand-alone. For Post Graduate Taught/iBSc students whilst on occasion these will be conducting stand-alone research many of these students will be conducting an element of an existing registered research project. The R&D office will check that the research they intend to undertake falls under the already approved project protocol.

PhD, MDRes and iBSc research which are clinical GOSH projects and are unfunded may need to be reviewed by the CRAC process as per section 5.6. In these cases the project may be eligible for the CRAC proportionate review process.

As per the HRA guidance universities and colleges should accept the role of sponsor for all educational research conducted by their own students, unless the student is employed by a health or social care provider that prefers to do this. Sponsors of educational research should ensure that their supervisors can and do carry out the activities involved in fulfilling this role.

Students should not normally take the role of Chief Investigator at any level of study, as this function should be undertaken by supervisors or course leaders. The exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt for a fellowship.

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Student projects that require HRA approval (including if applicable a NHS ethics review) require R&D review as per section 5.1. Student projects not requiring HRA approval (and/or a NHS ethics review) require R&D review as per section 5.2.

For a NHS staff study contributing to an external University student project (including UCL (ICH)) **and performed solely at GOSH,** as per the HRA guidance the project will not require HRA assessment as the existing local arrangements will apply. In this case the local review by R&D will be completed as per section 5.2. If the NHS staff study contributing to an external University student project (including UCL (ICH)) is NHS multicentre, then HRA approval should be sought by the sponsor. NHS ethics review is not required for NHS staff studies however University ethics approval may be required.
The HRA guidance on student projects is outlined in Appendix 7.

On occasion it would be necessary to issue provisional R&D approval to allow the PI to access the funding for the payment of a stipend for the student. ICH finance will contact R&D at least 1 month in advance of the student starting requesting R&D provisional approval to be issued for this if the relevant paperwork/approval is not in place. In those situations where the project is registered within 1 month of the student starting then ICH finance may request R&D provisional approval to be issued upon registration. The issuing of R&D provisional approval needs to be agreed with the Head of Governance, Clinical Trials and Contracts or the Research Governance Manager.

5.5 Records

All documentation relating to the R&D approval or confirmation of capacity and capability of a research study should be retained by the Joint R&D Office. Some documentation may need to be stored as hard copy in the Office such as Agreements/Contracts; the rest may be appropriately stored electronically.

Documents that are reviewed for R&D approval/confirmation of capacity and capability should be stored in the appropriate section of the document store on ReDA/EDGE (Please refer to Appendix 8 for ReDA/EDGE file structure) where appropriate.

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All documents (both zip files and individual files) should have a description. This is particularly important where the file name is not intuitive. **Zip files should only be used for storing groups of documents that have an association with each other.**

5.6 GOSH Clinical Research Adoptions Committee (CRAC)

The GOSH Clinical Research Adoptions Committee (CRAC) is an internal peer review committee that meets to review and endorse any clinical research projects taking place within Great Ormond Street Hospital (GOSH) that are not externally funded ('own-account projects'). The committee aims to ensure the standard and quality of clinical research within GOSH.

For those GOSH clinical research projects (sponsor or host site) which are not externally funded and the application for **Health Research Authority (HRA) approval is pending** then the PI/researchers should be given guidance to apply to CRAC.

For those clinical research projects where GOSH is the host site (and not sponsor), which are not externally funded, and **HRA approval has been granted**, then CRAC review is not required. In these situations it is assumed that adequate peer review has been completed by the sponsor for the HRA application. The research governance team will perform the assess, arrange and confirm review and confirm capacity and capability as per section 5.1.2.

For guidance please refer to Clinical Research Adoptions Committee (CRAC) SOP.

5.7. Research Passports

Some UCL-ICH employed researchers who are clinical academics will have obtained an honorary contract from GOSH-HR and so will not require a research passport.

Where non - GOSH researchers wish to gain access to GOSH in order to conduct their research; it is possible that they will require either an Honorary Research Contract (HRC) or a Letter of Access (LoA) in order to do so. If this is the case then the following will form part of the study review process. For guidance please refer to SOP for Research Passports, Letters of Access & Honorary Research Contracts.

Please note that persons accessing GOSH identifiable data at ICH/UCL will require an honorary research contract in place.

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6. Related Documents

NA

7. References

UK Policy Framework for Health and Social Care Research V3.3 07/11/17,

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

ICH Harmonised Tripartite Guideline for Good Clinical Practice E(R1). Published by The Institute of Clinical Research. ISBN-13;9-781905-238408

http://www.uclpartners.com/our-work/nihr-clinical-research-network

Health Research Authority approval https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/

NIHR research passports http://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/

https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-you-need-do/transparency/

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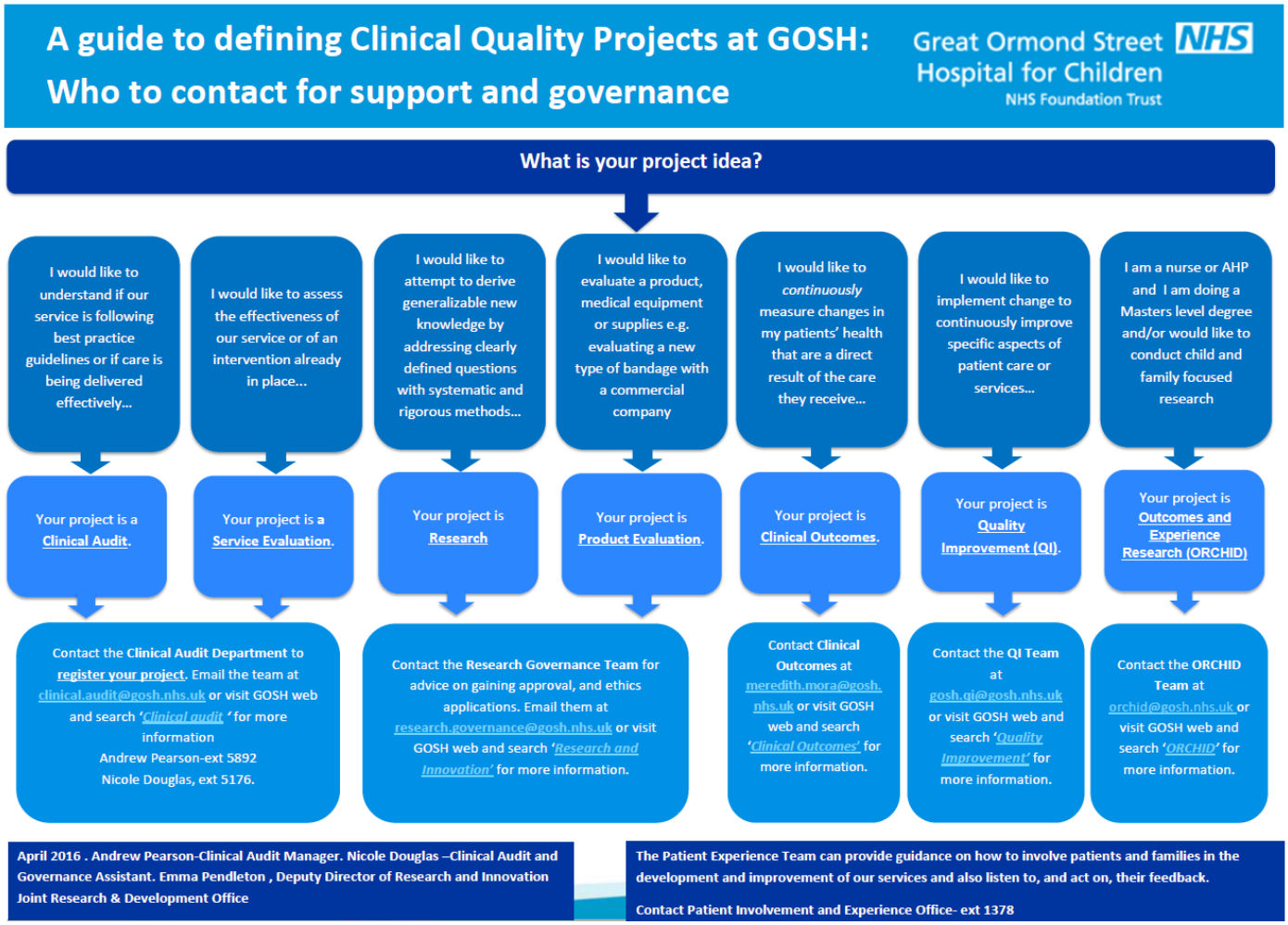
Appendix 1: A guide to defining Clinical Quality Projects at GOSH



Appendix 2: GOSH/ UCL-ICH risk based approach for confirming capacity and capability/Trust authorisation for HRA approved studies

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Type of Research- Based on IRAS category	Who confirms capacity and capability/Trust Authorisation
Clinical trial of an investigational medicinal product	• Head of Governance, Clinical Trials, and Contracts (for commercial and non-commercial studies) • Deputy Director of Research and Innovation (for Commercial and Non Commercial studies) • Clinical Trials Manager (for Commercial and non-commercial GOSH sponsored studies) • Research Governance Manager (Non-commercial studies)
Clinical investigation or other study of a medical device (not used within its CE marked purpose)	• Head of Governance, Clinical Trials, and Contracts • Deputy Director of Research and Innovation • Clinical Trials Manager • Research Governance Manager
Combined trial of an investigational medicinal product and an investigational medical device	• Head of Governance, Clinical Trials, and Contracts • Deputy Director of Research and Innovation • Clinical Trials Manager • Research Governance Manager
Clinical investigation or other study of a medical device used within its CE marked purpose	• Clinical Trials Manager • Research Governance Manager • Research Management and Governance Officer
Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice	• Head of Governance, Clinical Trials, and Contracts • Clinical Trial Manager • Research Governance Manager • This may be delegated to an Research Management and Governance Officer by the above authorised personnel

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Type of Research- Based on IRAS category	Who confirms capacity and capability/Trust Authorisation
Basic science study involving procedures with human participants	• Research Governance Manager • Research Management and Governance Officer
Study involving qualitative methods only	• Research Governance Manager • Research Management and Governance Officer
Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)	• Research Governance Manager • Research Management and Governance Officer
Study limited to working with data (specific project only)	• Research Governance Manager • Research Management and Governance Officer
Research tissue bank	• Research Governance Manager/ Research Management and Governance Officer providing ICH-HTA Committee Secretariat
Commercial study	• Head of Governance, Clinical Trials, and Contracts • Deputy Director of Research and Innovation • Clinical Trials Manager

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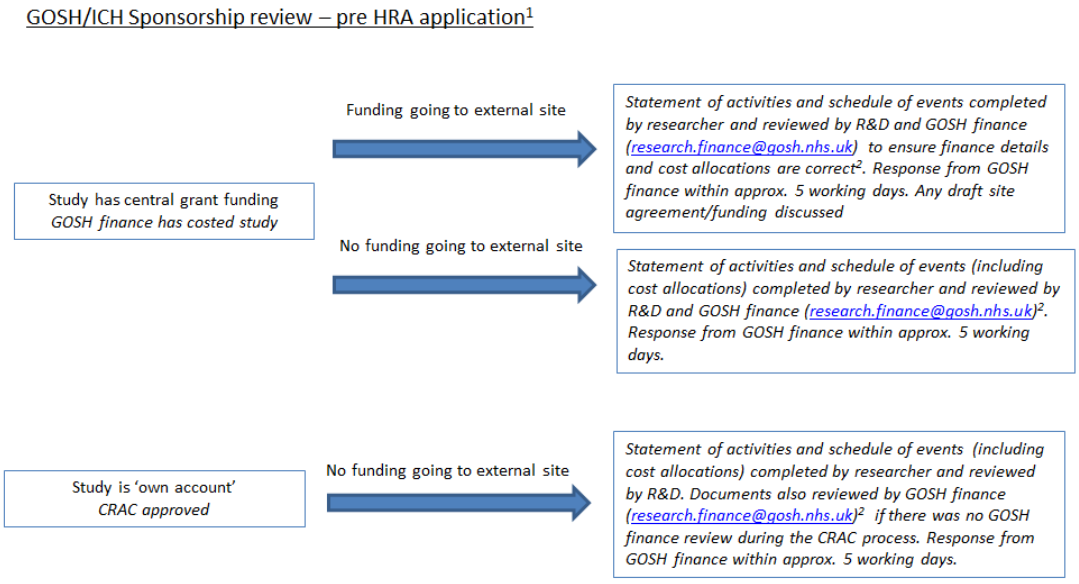
Appendix 3: Finance workflow



[1]*Applicable for multi-centre studies. Those studies in which is single site (which is also the sponsor) or those that the sponsor is a university and the single site is the NHS Trust linked to the sponsor through a joint R&D research office arrangement do not require the statement of activities or schedule of events to be submitted to the HRA. In GOSH/ICH sponsored multi-centre studies these documents are also not required for the GOSH site only.*

[2]*Minimum document sent to be provided to Finance is IRAS form, Statement of Activities and Schedule of Events.*

HRA (Health Research Authority approval) for research: Process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments' Research Ethics Service

CRAC: GOSH Clinical Research Adoptions Committee (reviews 'own account' unfunded studies)

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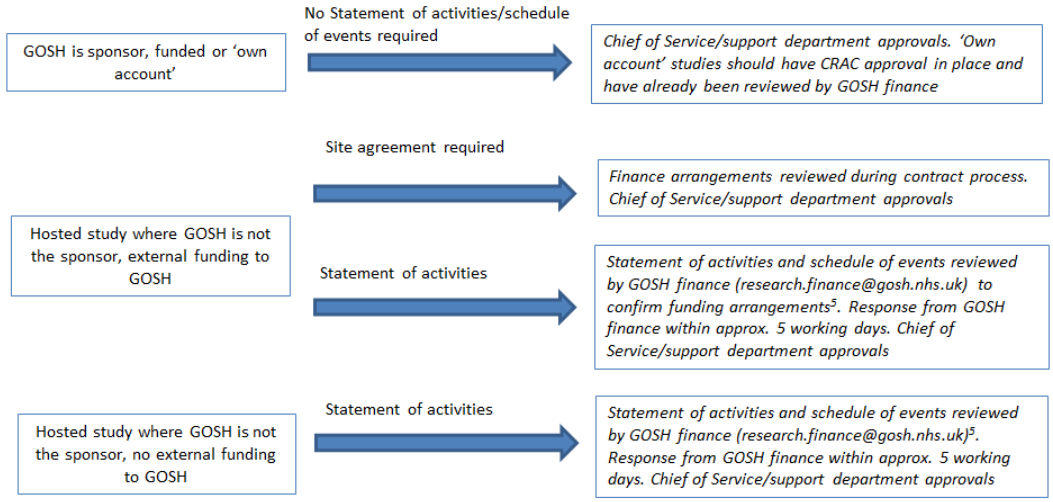
Assess, arrange and confirm review for GOSH[3] (non-portfolio)[4]



Notes:

[3] *Initiated after HRA approval has been issued for the study.*
[4] *For portfolio studies the AAC review is performed by the network. The finance aspects (including cost allocations) are checked by the network costings/finance officer and this information is provided to the Chief of Service and other support departments for approval of the study.*
[5] *Minimum document sent to be provided to Finance is IRAS form, Statement of Activities and Schedule of Events.*

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Appendix 4: GOSH Chief of Service Authorisations (as of 11/12/2018)

Division	Specialty	(Clinical)Departmental Authorisor	Email
Brain	Neurology	Dr Sophia Varadkar	Sophia.Varadkar@gosh.nhs.uk
	Neurosurgery		
	Neuromuscular		
	Epilepsy		
	Neuro-disability		
	Neurophysiology		
	Endocrinology		
	Metabolic		
Body, Bones and mind	Nephrology	Dr Allan Goldman	Allan.Goldman@gosh.nhs.uk
	Urology		
	Gastroentrology		
	SNAPS		
	CAMHS		
	General Paediatrics		
	Orthopaedics		
	Spinal		
Operations and Images	Imaging	Eithne Polke	Eithne.Polke@gosh.nhs.uk
	Anaesthetics		
	Pain		
Sight and Sound	ENT	Dr Elizabeth Jackson	Elizabeth.Jackson@gosh.nhs.uk
	Audiology		
	Cochlear		
	Opthalmology		
	Plastics		
	Dental and Maxilofacial		
Blood, cells and cancer	Oncology	Dr Clarissa Pilkington	Clarissa.Pilkington@gosh.nhs.uk
	Haematology		
	Haemophilia		
	Palliative Care		
	Immunology		
	Bone Marrow Transplant (BMT)		
	Infectious Diseases		
	Rheumatology		
	Dermatology		
Heart and Lung	Cardiology		
	Cardiac Surgery		
	Respiratory		
	PICU/NICU/CICU		
	CATS	Dr Daniel Lutman	Daniel.Lutman@gosh.nhs.uk
Medicines, therapies and tests	Pharmacy/BME	Dr Allan Goldman	Allan.Goldman@gosh.nhs.uk
	Physiotherapy		
	Occupational Therapy		
	Speech and Language Therapy		
	Dietetics		
	Psychology		
	Lab Medicine		
	Genetics		
International and Private Patients	International and Private inpatients and outpatients	Dr Melanie Hiorns	Melanie.Hiorns@gosh.nhs.uk

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Appendix 5: Governance list of checks for Research Studies conducted by or at ICH-UCL (this includes studies that may use NHS tissue or data approved for future research under an overarching REC favourable opinion Letter)

Documents to request	Why
Research Conducted or Sponsored by ICH-UCL (including retrospective collections of tissue and data from NHS Patients)	
Research Protocol/ Funding Proposal	This is a description of the proposed research activity to be conducted, who it will involve and what resources will be used. It serves as the basis for making a determination of what is required to be in compliance with local policy, the RGF, and any applicable legislation.
REC favourable opinion Letter from NRES (for use of NHS tissue or data in research project that is under review)	This document is required when previously collected human tissue or data from NHS patients is to be used for laboratory based research. This document serves as confirmation that the Ethics is in place for the use of the data or tissue referred to in the Protocol. In some instances, a copy of the protocol, or REC application and PIS and ICF may be required for clarification on what is actually covered by the REC favourable opinion letter.

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Documents to request	Why
Copy of REC* application, REC* Approval letter(s), Participant Information sheets and consent/ assent forms (correct version & dates). **This could be a University or overseas REC.*	A UCL ethics approval letter is required for all research studies sponsored by ICH that involves the use of tissue and data from non-NHS Participants (the exception is research that falls under the MCA (2005) as this needs to reviewed by an NHS REC), or where a REC favourable opinion (issued by NRES/HRA) is in place to cover the research. These documents provide evidence that the research activity is approved as well as what research activity and data collection tools will be covered by the REC approval.
Approval from the Confidentiality Advisory Group (CAG) previously called the National Information Governance Board (NIGB).	ICH conducts studies for various Governmental bodies which occasionally require the use of patient identifiable data without consent. The CAG approval letter will be required if gaining access to and using identifiable patient data without the consent of the patients.
Approved Risk Assessment	Required for all ICH based studies, however this should not hold up R&D approval letter if all other checks are in place. Where a risk assessment has not been applied for or has not yet been approved a conditional R&D approval letter may be sent to the PI and a copy of this sent to the ICH Head of Laboratory Management for their follow-up.
Data Protection Assessment Form	Where data is being transferred from the NHS setting into ICH-UCL and this data is identifiable, or is pseudo-anonymised, the Data Protection Assessment Form must be completed and reviewed by the Data Protection Team at UCL and the Caldicott Guardian at GOSH (if applicable).

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Documents to request	Why
Other	These will be project dependent but may include: • Material Transfer Agreement (where human tissue is being transferred between organisations May also need to follow up for: • Supplementary information to the protocol/ proposal For UCL data studies then additional checks include: • Review database websites/information for access arrangements • Confirm if data-agreement will be required Confirmation of relevant local unit, facility and equipment use approvals or agreements.

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Appendix 6: Product evaluation review flowchart

Complete the Product Evaluation Form found here and submit, along with the Chief of Service approval for the project and short protocol/plan, to research.governance@gosh.nhs.uk

The documentation will be reviewed by the research governance team and submitted to the Health Research Authority (HRA) for opinion

If your project is Research
If the HRA classify the study as research, approval will need to be sought following the standard research processes. Please see http://www.gosh.nhs.uk/research-and-innovation/information-researchers/joint-research-and-development-office-rd for more details.
The R&D office will guide you through the process of obtaining the necessary approvals in order to begin your study at GOSH.

If your project is NOT Research
If the study is not classified as research it will be submitted to the GOSH Medical Equipment Supplies Group (MESG) for considering and approval. This group meets monthly

Where third parties are involved it is the responsibility of the GOSH study lead to ensure appropriate agreements are in place, including but not limited to data sharing agreements (advice can be sought from the GOSH Information Governance Officer or Information Governance Manager).

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Appendix 7: HRA guidance on student projects

(As of 11th December 2018 https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/)

Student studies are those undertaken primarily for the purpose of obtaining an educational qualification. Studies where the main purpose is to undertake specific research – and the educational qualification is secondary – do not fall into this category.

Student research should be approached in the same way as other studies taking place in the NHS. HRA Approval should be sought for any educational study led from England that:

- requires review by an NHS Research Ethics Committee (REC)
- is taking place across more than one NHS organisation
- is applying for support from the NIHR Clinical Research Network.

Exemptions

For educational studies taking place at a single NHS site in England and which **do not** require REC review, the NHS organisation and the university sponsoring the research will usually have an existing understanding about how these types of studies are handled.

For these studies, there are two options depending on existing local arrangements:

1. Where universities and NHS organisations currently do not require an IRAS form to be submitted to the NHS R&D office but have alternative arrangements in place, these may continue.

2. Where universities and NHS organisations currently do require an IRAS form to be submitted to the R&D office, then an application for HRA Approval should be made. A template Statement of Activities and template Schedule of Events will not be needed as there is not likely to be the need to attribute funding. Such student studies will be reviewed against the same HRA assessment standards and criteria as other studies. It is expected that the sponsor will provide any advice and support to students using this process.

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Appendix 8: ReDA/EDGE file structure

REDA File Structure
1. Current Protocol 1.1 Superseded Protocols
2. Finances/Grant R&D registration form 2.1 Registration 2.2 CRAC
3. Contracts/Agreements
4. R&D / Sponsorship 4.1 R&D Form 4.2 SSI Form/Authorisation 4.3 R&D Approval Letters 4.4 Sponsorship Letter 4.5 Risk Assessment 4.6 Pharmacy Review 4.7 Peer Review 4.8 Indemnification/Insurance
5. Local Study Documents 5.1 Superseded
6. MHRA 6.1 CTA Application form 6.2 MHRA notice of acceptance 6.3 Amendments
7. Ethics 7.1 Application 7.2 Approvals and Letters 7.3 Amendments
8. Pharmacovigilance 8.1 Safety Reports 8.2 DSUR/APR
9. Monitoring/Audit/Inspection
10. Investigational Medicinal Product 10.1Current IB/SmPC 10.2Superseded IB/SmPC 10.3Example of labels/prescriptions 10.4Accountability/Storage/Temperature records 10.5 Dispensing procedures/SOPs
11. Laboratory & Equipment 11.1List of laboratories with their normal ranges 11.2Accreditation 11.3Sampling 11.4Equipment codes/calibration certificates
12. Correspondence
13. Other Documents
14. Final Report/Publications

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