
# Project Set Up and Delivery

SOP v1.1

# Introduction

This document covers guidance for the Set Up and Delivery of multi-centre pan-London projects as part of the London REACH (Research, Evaluation and Audit in Child Health) network.

The process for project submission, evaluation and selection is detailed in the Project Selection Process Standard Operating Procedure document.

| This policy should be considered together with other REACH Network policy documents (available via our website), including: |
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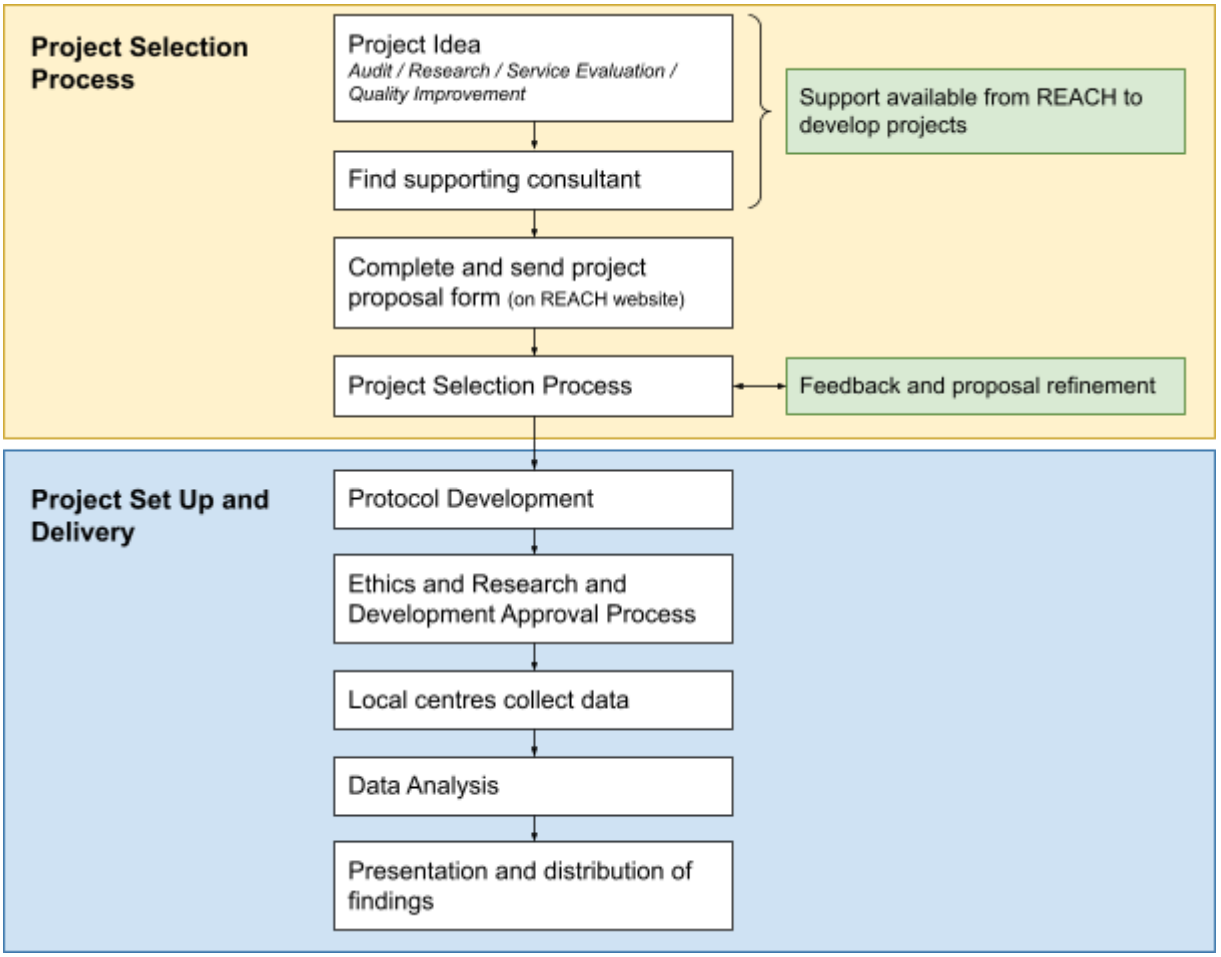
| - Our Constitution |
| - Project Selection Process - Standard Operating Procedure |



Projects selected through the Project Selection Process then enter a phase of development - Project Set Up and Delivery. During this phase, a detailed protocol describing the operation of the project in its entirety is developed.

# Allocation of Roles and Responsibilities (Step 1)

The first step in Project Development is identifying and assigning roles for the project leadership team.

The roles that will be required and the number of individuals filling each role will vary depending on the complexity and scale of the project being undertaken.

Likely roles to be assigned include:

**Project Lead(s)**

The proposer of the project will be the first choice for Project Lead, either alone or with a co-lead chosen by the proposer and central committee. If the proposer declines, the Central Committee will work with the proposer to identify a suitable lead(s).

The project lead will be responsible for leading on and coordinating all aspects of the project, from inception through to dissemination of results. This includes, but is not limited to:

- Background literature review (if applicable)
- Protocol design
- Regulatory approval
- Case Report Form (CRF) design
- Analysis strategy
- Dissemination strategy

In addition to study design considerations, the Project Lead has important organisational responsibilities, including but not limited to:

- Coordinating with the Project Subteam, including Consultant Lead
- Coordinating with the REACH Central Committee
- Monitoring project timeline and milestones

The Project Lead(s) will, at all times, be supported by the Consultant Lead, Project Subteam & REACH Central Committee.

If at any point the Project Lead(s) is unable to fulfil the responsibilities of this role, the Central Committee will support them in identifying additional support or a new lead(s).

**Consultant Lead(s)**

Ideally, a consultant lead will already be in place at the submission of the project proposal. The consultant should work within the project area and be happy to support all aspects of the project.

Though the projects we select and develop are trainee led, having robust support from a Consultant Lead is invaluable. Project Consultant Leads must be invested in the project and willing to provide advice and guidance for those working on the project. They can be supported by Consultants that support the REACH Central Committee more generally.

**Project Subteam**

The Project Subteam will be made up of the Project Lead(s), Consultant Lead and self-selecting members of the Central Committee. They will form the core working group for all aspects of the project and support the workload of the Project Lead(s). In the event that more members of a Project Subteam are required, the Central Committee will help advertise and recruit from the London region of paediatric Junior Doctors.

Organisation of the Project Subteam will fall to the Project Lead and REACH Chair(s). Specific roles within the Project Subteam may be allocated if appropriate.

The Project Subteam will also work alongside other members of the REACH Network - including Local Teams and the Central Committee.

**Project Local Leads (Consultant and Junior Leads)**

- Coordinate and conduct the study locally - including liaising with local regulatory bodies
- Liaise with local supervising leads
- Liaise with Project Subteam
- Monitor progress with respect to project timeline and milestones
- Present data locally
- Organise and lead project team meetings at an appropriate frequency which may be as much as be weekly during certain project phases.

**REACH Central Committee**

- Support Project Leads by giving advice on methods and the running of the project
- Regulatory and compliance monitoring
- Recruitment and communication with Local Leads and Local Consultants
- Dissemination of relevant information via the REACH Newsletter & Social Media
- Supporting project design, set up, data collection, analysis and dissemination
- Optimising patient and public involvement throughout the project

It is essential that the key responsibilities of each of the roles within a project are clearly outlined and agreed upon prior to the commencement of the project.

# Project Development (Step 2)

Once the project team has been assigned, the Project Subteam begins Project Development. This involves working on the core design of the project and developing key organisational documents.

These organisational documents include, but are not limited to:

- Project timeline and Gantt chart
- Study protocol
- Case Report Form

These documents may be made available to the public or interested parties for the purposes of transparency and auditing.

In addition, in this phase, it is expected that regulatory requirements are considered in full, with appropriate approvals requested. This may include:

- Protocol registration
- Research Ethics Committee review and approval
- Integrated Research Application System (IRAS) registration
- Information Governance compliance

If there is uncertainty regarding regulatory requirements, there are online tools and resources for guidance in most areas (1,2). In the case of ethics, it may in some instances be useful for the proposal and study design to be discussed with a Research Ethics Committee for their documented assessment to whether Research Ethics Committee approval would be required. Any regulatory issues must be discussed and resolved at a Central Committee Level.

**General Recommendations and Expectations**

- Data must be fully pseudonymised (if not fully anonymised) and comply with the EU General Data Protection Regulation (GDPR)
- It is recommended that data collection periods coincide with trainee rotation dates
- Data can be collected retrospectively or prospectively
- A timeline (Gantt chart) is recommended to aid project delivery
- Regular contact is made with individual data collection teams and problems identified early
- Regular contact is kept with the REACH committee

**Specific Considerations related to Information Governance**

Everyone involved in the design of the project or in data collection must ensure that the project complies with Data Protection Regulation and Caldicott principles:

1. Justify the purpose
2. Don't use patient-identifiable information unless absolutely necessary

3. Use the minimum necessary patient-identifiable information
4. Access to patient-identifiable information should be on a strict need-to-know basis
5. Everyone with access should be aware of their responsibilities
6. Understand and comply with the law
7. Understand that the duty to share information can be as important as the duty to protect patient confidentiality

Local Leads can legitimately access confidential clinical information for patients in their department, without the consent of the patient/guardian when carrying out an audit. Health care professionals outside of this clinical team cannot access this information unless it is pseudo-/anonymised. There is NHS England guidance on information sharing between NHS trust. It may be that approval is needed from an NHS Health Research Authority Confidentiality Advisory Group (CAG) – see 'Guidance for CAG applicants' (3).

There should be a plan regarding the time and manner of disposal of any patient identifiable information collected locally as part of the study.

# Project Execution (Step 3)

Once the protocol has been approved and appropriate regulatory agreements obtained, the project is then offered to participating centres within the network. Consultant and Junior Leads at each of the centres assist with local management of the project with oversight from the Project Subteam. The Local Leads are supported by additional Junior Doctors who may assist, for example, in data collection.

The local centres will have specific regulatory requirements, including needing approval from Audit and Research and Development departments. Local Leads will liaise with their appropriate regulatory departments with support from the Project Subteam.

Project timelines and milestones should be clearly defined and regularly reviewed and communicated with local teams to ensure appropriate progress is being made, with roadblocks quickly identified and escalated.

**Data Collection**
Data collection takes place at a local level by Junior Doctors supported by a named Lead Consultant Lead. Pseudonymised data should be sent to the project leads in encrypted spreadsheets. We suggest that unique patient identifiers are used for each patient, with three letters identifying the trust (e.g. RLH=Royal London Hospital, WHI=Whittington Hospital), followed by three numbers from 001. It is recommended for local Project Leads to keep a record between pseudonymised study numbers and identifiable data, in case there is the need to re-examine the data. Patient identifiable information should never leave the trust.

# Data analysis (Step 4)

All projects should have pre-specified analysis plans. These should be included in the project proposal form and refined in the detailed project protocol. Post-hoc analyses are not recommended, but if performed should be clearly specified as such in any presentation or publication.

Data analysis can be completed by the Project Subteam, additional support may be requested and provided by members of the REACH Central Committee or recruited from the wider REACH Network.

# Post Project (Step 5)

A final summary of the project including findings and learning from administrating the project should be submitted and uploaded on the REACH Website.

All findings should be distributed to the local centres and ideally presented internally by the local teams.

For audit projects, it is good practice to ensure the audit loop is closed. Following dissemination of the findings, a plan should be developed and disseminated suggesting appropriate changes to implement as well as how and when to assess for improvement following these recommendations.

In addition, it is hoped that additional outputs from the project can be achieved, including:

- Presentation at departmental clinical governance meetings
- Poster or oral presentation at regional meeting
- Poster or oral presentation at national meeting e.g. RCPCH conference
- Submission to peer-reviewed journals

# Authorship

The REACH Constitution provides clear guidance on our approach to authorship and giving recognition to those contributing to our projects.

# References


1. https://www.hra-decisiontools.org.uk/research/
2. https://www.hra-decisiontools.org.uk/ethics/
3. Guidance for CAG applicants. https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-adv

sory-group/guidance-confidentiality-advisory-group-applicants/ Accessed July 2021

# Acknowledgments:

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