Project Management

NJRO-GEN-SOP-022

Contents

1. Background/Introduction

Project Management is the discipline of planning, organising and managing resources to bring about the successful completion of specific project goals and objectives. The primary purpose of Project Management is to achieve all of the project goals and objectives, while honouring the project constraints, which typically are time, budget, quality and scope. A Project Manager works within these constraints to ensure that the right information is available at the right time for the right people to make the right decisions. The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) has dedicated Research Project Managers responsible for implementing Project Management on research projects/trials. When a Clinical Trials Unit (CTU) are involved, agreed Project Management tasks are delegated to the Trial Managers at CTU.

2. Purpose

The purpose of this SOP is to describe the principles of project management and give an example of a process for managing a clinical trial which covers project initiation, planning, delivery, monitoring, control and closure of studies and the actions and responsibilities required to undertake these steps. For the purpose of this SOP, the term 'project' encompasses all trials and studies where a NuTH Project Manager is allocated.

3. Scope of Document

This SOP should be followed by NuTH Project Managers and anyone delegated project management responsibilities.

4. Definitions

Funder - is the organisation or group of organisations providing funding for the research project

Chief Investigator (CI) – The person designated overall responsibility for the design, conduct and reporting of a study

CTU – Clinical Trial Unit – A specialised research unit which design, centrally coordinate and analyse clinical trials.

Project Management – The planning, delegating, monitoring and control of all aspects of the project to achieve the project objectives within the expected targets for time, cost and outcome.

Risk Assessment - Used to describe the overall process or method where: hazards and risk factors are identified that have the potential to cause harm to a project.

Gantt Chart – A high level, detailed bar chart illustrating a projects schedule: showing the major tasks, when they will be delivered and at what cost. The plan provides a schedule that helps to plan, coordinate and track specific tasks in a project.

Trial Management Group (TMG) – The Trial Management Group normally includes those individuals responsible for the day-to-day management of the trial, such as the Chief Investigator, Statistician, Trial Manager, Research Nurse, Data Manager who meet at regular intervals to oversee the running of the project.

5. Roles & Responsibilities

Sponsor - is responsible for the oversight of the project and Chief Investigator. Sponsor is responsible for supporting the CI to establish project management requirements before the appointment of a Project Manager (and/or Trial Manager if applicable) and to support the Project Manager in working with those requirements.

Project Manager (PM) - Responsible for day to day project management and supporting the Chief Investigator and Trial Manager.

Trial Manager (TM) – Responsible for delegated Project Management tasks within CTU.

6. Procedures

6.1. Project Planning

Project planning is extremely important in order to achieve a successful project and to keep control over the specialist work required within the project. Specifically all stakeholders must be clear on what their responsibilities are, what the project is intending to achieve, why it is needed and how the outcome is to be achieved. As a starting point, using the information available about the Project the Project Manager (PM) will be asked to calculate what percentage of their time they will allocate to the project (e.g. full time, 1 day a week) – this will depend on other commitments and the complexity of the tasks the PM will be responsible for as agreed with the CI. The 'Division of Responsibilities' can be used to identify who will be responsible for each task so the PM can calculate a percentage.

At this stage PM tasks include:

- Establishment of the Project Managers roles and responsibilities
- Support CI and act as main point of contact for all stakeholders.
- Early contact and engagement
- PM forecasting
- Create project plan - plot milestones and key deliverables

6.2. Project Initiation

Once resources have been agreed, the project initiation stage can start.
This stage ensures that the scope of the project is clarified and the resources reviewed so that the final contract agreed with the funder and sponsor is appropriate to ensure that the project is effectively delivered.

Key aspects of project initiation that the Project Manager will support include:

- Assist with completing documents (e.g. IRAS and Patient Documents, etc) for submission to the necessary regulatory committee (e.g. HRA, REC, MHRA, etc.)
- Register Trial (IRSCTN, Portfolio, Research Fish, etc).
- Risk Management (including necessary steering committees are in place).
- Development of budget (money & time) management system
- Assist with compiling documents for Sponsorship approval
- Set-up sites in accordance to local R&D: support set-up process, gain local approvals
- Ensure necessary contracts are in place: Collaboration/Site/Vendors.
- Establish funder reporting requirements
- Development of the Gantt chart

6.3 Project Delivery

Delivery of the project will use the processes, timescales and key deliverables defined in the project planning stage to deliver the research question identified in accordance with the project plan.

Throughout the duration of the project, project delivery may include:

- Project reporting: Funder reports, REC reports, etc.
- Manage the Project Plan and report to TMG the milestones and key deliverables
- Budget and resource management, including invoicing
- Manage procurement/supplies for project
- Site monitoring as appropriate (intensity depends on nature of trial which will have been agreed through study approval). PM posts will be trained on monitoring before undertaking this task.
- Labs and sample management
- Monitor recruitment

6.4 End of project

The end of the project is defined in the protocol. The sponsor will be informed of any changes to the end date of the project; documentary evidence will be required.
Project closure should not take place before formal acceptance of the end of the project by the project funders.

End of project tasks will include:

- Declaration of end of study to the regulatory bodies (REC, HRA, MHRA)
- Financial reconciliation
- Close down of sites
- Ensure Final report is completed
- Ensuring Final report are distributed as appropriate
- Ensure study files are approved for archiving

6.5 Monitoring and control

Monitoring and control comprises those processes necessary to understand how the project and its products are progressing and ensure that potential problems can be identified in a timely manner and corrective action taken.

Monitoring the project can be in the forms:

- On site monitoring (as defined in monitoring plan)
- TMG's – regular meeting as defined in project plan
- Corrective and Preventative Action plan (CAPA)
- Root Cause Analysis

7. References

HRA (2017) UK policy framework for health and social care research.
Axelos (2017) *Managing successful projects with Prince 2*.

8. Appendices

Not applicable