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SOP10: Standard Operating Procedure for Project Management

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Approved by WWORTH JMG (Ian Russell in chair) on 13 March 2009

Signature_____   Date_____

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0	16 Jul 2009	Creation
0.1	19 Jul 2009	Further amendments
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0.3		Further amendments
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2   Glossary

The full Glossary is in Swansea University H drive/Documents/526-WWORTH/Development Group/Glossary. The terms of particular relevance to this SOP are:

Product	An input or output, whether tangible or intangible, that can be described in advance, created and tested. A product may be tangible like a printed publication or a website, or it may be less concrete like a training course or some form of service or approval. It may be part of the final outcome or an intermediate element which is essential to the work of delivering a project. Plans, communications, case report forms and quality checks are all examples of products, which may also comprise a collection of other products (eg a quality plan may comprise criteria, approval process and checklists).
Product Breakdown Structure	A hierarchical structure that breaks down a final product into its constituent sub-products.
Product Dependency	When a product is dependent upon the development / completion of another product.
Product Description	A structured format of presenting information about a project product consisting of a description of a product's purpose, composition, derivation and quality criteria. It is written as part of the planning process, as soon after the need for the product is identified to ensure that the people involved know why it is needed, what it will look like, from what sources it will be derived and the quality specification of the product
Scope	Defines the boundaries of a project (what is and is not expected of a project). The scope of products can also be defined.
Stakeholder	Anyone who has an interest or involvement in a project.
Task	Something that needs to be done to complete a product of the project. Can be split into sub-tasks.

3   Introduction

Standard Operating Procedures (SOPs) are succinct formal documents designed to achieve consistency in specified trial functions by specifying standard practice in performing those functions (GCP 1.55 & 5.1.1 – EMeA,

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2002). While SOPs should cite relevant legislation & regulations, and key references & evidence, they need not expound theory.

WWORTH SOPs should accord with all relevant regulations, including the European Union Clinical Trial Directive, ICH Good Clinical Practice (GCP) and the current NHS Research Governance Framework. They will seek to distinguish between regulations for CTIMPs and for other research.

This document forms part of the set of Standard Operating Procedures (SOPs) of the West Wales Organisation for Rigorous Trials in Health (WWORTH) and describes the roles, responsibilities and actions necessary for the effective management of randomised trials and other rigorously designed studies.

4   Purpose

The purpose of this SOP is to describe the principles of project management and give an example of a process (partly derived from the project management methodology, PRINCE2) for managing a clinical trial which covers project initiation, planning, execution, monitoring, control and closure of studies undertaken with the support of WWORTH, and the actions and responsibilities required to undertake these steps. For the purpose of this SOP, the term 'project' encompasses all trials and studies adopted by WWORTH.

5   Roles and Responsibilities

The Chief Investigator is responsible for the overall delivery of the project and for the effective implementation of this SOP, with the support of the TM/TC. All members of the project team are required to follow the processes and procedures set out in the SOP.

Trial Manager/Trial Coordinator is responsible for day-to-day project management.

All members of the trial team are responsible for effective application of project management principles.

Trial Administrator is responsible for maintaining appropriate systems for the effective application of project management principles.

WWORTH Manager is responsible for supporting the CI to establish project management principles before the appointment of a TM/TC and to support the TM/TC in working with those principles.

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6   Procedure

6.1   Flow chart for project management

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6.2   Principles of Project Management

Project Management (PM) is the discipline of planning, organising and managing resources to bring about the successful completion of specific project goals and objectives. The primary challenge of PM is to achieve all of the project goals and objectives, while honouring the project constraints, which typically are time, budget, quality and scope. A successful project will be completed on time, on budget and with specified quality measures.

Effective project management should:
- Clarify what has to be achieved
- Clarify roles and responsibilities
- Focus on shared goals
- Plan, monitor and control the budget
- Plan, monitor and manage or co-ordinate human resources necessary for project completion
- Minimise risk
- Communicate to all involved
- Manage change
- Ensure that dependencies are identified and completed
- Ensure that original project objectives are met and planned outputs delivered OR are renegotiated and amended with the project commissioner and then met, with amended outputs delivered

Within WWORTH, the person responsible for implementing PM will usually be the TM and where possible this person should be involved at the earliest stages of project planning.

6.3   Development of research proposal

When a research proposal is conceived, a protocol is developed and bid for funding drawn up (see WWORTH SOP13 Protocol Development). Project management issues should be identified and the funding applied for should include adequate resources for PM.

A risk assessment should form part of this process (see WWORTH SOP31 Sponsorship and Adoption) which should include:
- Identification of the sources of risk (Appendix 1)
- Assessment of the likelihood of risk
- Assessment of the magnitude of risk
- Development of a response
- Documentation of the process

At this stage, all stakeholders should be identified and their roles and expectations clarified and agreed.

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The research proposal will also include an estimate of timescales. These should be estimated realistically taking into account major dependencies and presented as a high level Gantt chart (see Appendix 2).

6.4   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 is appropriate to ensure that the project is effectively delivered. The roles and responsibilities of the CI and TM/TC with respect to project management should be explicitly formulated at this stage. A TM may not be in place at this stage; the WWORTH Manager may work with the CI and other staff as appropriate in the meantime.

Key aspects of project initiation include:

- Contracting and subcontracting

- Recruitment of staff

- R&D & information governance and ethics processes and regulatory processes if appropriate (WWORTH SOP14 Ethics Approval, WWORTH SOP15 MHRA Approval)

- Support or approval of professional bodies

6.5   Project planning

The following sections outline a recommended approach to project management. Project planning should ideally start before the contractual start date. It will include:

- Establishment of the project management structure (Appendix 3)

- Identification, development and management of products (Appendices 4 & 5) (including issue and risk logs – Appendices 1 & 6))

- Identification of product dependencies

- Development of a project management plan or Gantt chart

- Development of budget (money & time) management system

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6.5.1 *Establishment of the project management structure*

The independent Trial Steering Committee (TSC) will oversee the overall direction of the project (see WWORTH SOP17 Monitoring).

The independent Data Monitoring and Ethics Committee (DMEC) will have responsibility for monitoring data quality and patient safety, reporting to the TSC (see WWORTH SOP17 Monitoring and WWORTH SOP09 User Inclusion).

The management of the trial will be overseen by a Trial Management Group (TMG), usually chaired by the Chief Investigator (CI). The TMG should include team leads, e.g. lead statistician, qualitative lead, outcomes lead. The TMG should meet at regular intervals and receive structured reports on progress (Appendix 7) from team leads. The TMG will report to the TSC. See Appendix 3 for an example of a project management structure although the exact structure will vary from project to project.

Advisors, external reference groups and stakeholders should all be included in the planning process.

6.5.2 *Identification, development and management of products*

The starting point for managing a project effectively is to have a clear understanding of what you are trying to achieve. This can be thought about in terms of products. Products are what are created to achieve a project and can be final or intermediate. An example of a final product is the 'Final Report'; an example of an intermediate product is 'Ethical approval obtained'. A starting point would be for the project to define what the desired products are. This requires 'starting with an end in mind' and should focus the project planning.

At an early stage all the necessary products of the project should be identified. This can be achieved by bringing members of the project together to use brainstorming processes. 'Post-it' notes can be used to record the products. The 'Post-it' notes can then be used to create a product breakdown structure - a structure that breaks down a final product into its constituent sub-products. This helps to clarify all necessary work to achieve the final product.

The products to be developed should be project plans addressing communication, documentation (see WWORTH SOP01b Document Control), financial procedures, quality (see WWORTH SOP18a Quality Management) and analysis, followed by specific products to meet the needs of the study from start to finish, including publication plans (see WWORTH SOP29 Trial Reporting).

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Products should be described in a Product Description (a proforma, Appendix 4 and an example, Appendix 5 are attached.), including purpose, scope, composition, derivation, format, presentation and quality assessment. The author of a Product Description should be the person responsible for the product and it should be agreed by the TMG.

Project documentation will be kept in accordance with WWORTH SOP01b Document Control. From the project management perspective it will include project plans, product descriptions, roles and responsibilities of research team, agendas and minutes of meetings, reports, issue and risk logs.

Separate Risk and Issue Logs should be established (see examples Appendix 1 and 6) to record risks to the effective completion of the project and issues which need to be addressed (see WWORTH SOP31 Sponsorship and Adoption and WWORTH SOP32 Misconduct). The Risk Log should be derived from the initial risk assessment undertaken during project development (see WWORTH SOP31 Sponsorship and Adoption). Each risk and issue should be allocated a unique number, dated, described, accorded an appropriate status (e.g. Issue – High, Medium, Low. Risk – closed, reducing, increasing, imminent, no change). The Logs should be reviewed at each TMG and TSC. Details of risks and issues that have been closed must be retained but can be moved to a separate spreadsheet.

6.5.3 *Identification of product dependencies*

The product breakdown structure can be used to determine the sequence in which products should be produced and the interdependencies between them. Flowcharts are an effective way of illustrating these interdependencies using arrows flowing in the appropriate direction(s) to and from products.

Identification of product dependencies will enable time-scales to be clarified and ensure essential pieces of work are not omitted. For example, research activity at a trial site is dependent on local approvals; local approvals are dependent on approval from REC (see WWORTH SOP14 Ethics RG Approval) and MHRA (see WWORTH SOP15 MHRA Approval); the latter are dependent on a study protocol being submitted to REC and MHRA for approval.

6.5.4 *Development of a project management plan or Gantt chart*

Once products have been described and their dependencies identified, the tasks needed to achieve the products can be identified and the duration of these can be estimated. A detailed Gantt chart can then be developed (see example Appendix 2). Projects should be divided into phases with

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clear completion dates of each phase, at which progress should be reviewed by the TSC.

6.5.5 Development of budget (money & time) management system

In addition to the TSC, DMEC and TMG, PM controls should be developed that are consistent with the risk and complexity of the project. These should include mechanisms to monitor project finances and resources and a process to manage change (see 6.7).

Expenditure should be monitored against planned expenditure and any discrepancies discussed with the sponsor or funder.

6.6 Project execution

Execution of the project will use the products (usually processes of some sort) defined in the planning stage to deliver the final product(s) identified in accordance with the project management plan.

6.7 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 (see WWORTH SOP17 Monitoring and WWORTH SOP18a Quality Management).

A clear change management policy should be identified for the assessment and authorisation of any changes to the project. This should include: a process for recording change requests; a process for accepting or rejecting change requests; methods for preventing unauthorised changes; a system for informing appropriate stakeholders of changes.

Monitoring of products can be done using their Product Description as a basis for what was specified and comparing it to the product actually developed to determine whether it has deviated outside tolerable levels (which are stated in the Product Description). An appropriate member of the TMG, should assess the quality of any product and it should not be the product owner (see WWORTH SOP18a Quality Management).

6.8 Project closure

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 final product by the project funders. The sponsor will be notified about project extension and closure.

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For the majority of projects execution of the publication plan and dissemination plan will continue after the project funding has finished.

7 Training Plan

All WWORTH staff involved with trials must undertake the appropriate generic and trial-specific training to ensure that they meet with the specific employers' mandatory training requirements and the specific requirements of the trial. For example, for SU staff, all new employees must attend induction, fire and safety training (as well as role-specific training courses, e.g. laboratory safety). For new staff, additional training requirements should be identified alongside the specific role requirements and the WWORTH Unit Manager should make provision for the new staff member to attend the necessary courses as soon after appointment as is practicably possible.

It is the responsibility of the WWORTH Unit Manager (alongside the CI or TM) to identify all the SOPs that are relevant to a specific trial and in which the new member of staff should be trained. The WWORTH UM or the SOP author will provide group training for trial staff and/or one-to-one training, as required for new staff in relation to the specific SOPs identified. Training records should be filed both by the main employer and the staff member, in accordance with the specific employer requirements. Trial specific training should be filed in TMF or TSF as appropriate and every individual involved in a trial should have an individual training record (see WWORTH SOP02 Training).

Where the tasks specified in the individual SOPs are delegated to WWORTH staff, CIs/PIs or TMs, these delegated staff must ensure that they have attended a training course on GCP and keep up-to-date through attending refresher courses.

It is the responsibility of the CI/PI to ensure that all staff allocated duties on the study delegation log template of responsibilities are suitably trained in the activities linked to those duties (see WWORTH SOP16 Site Setup, Appendix 9 and Appendix 10).

Each trial should maintain a central training log and ensure that WWORTH has access to that log, not least to integrate the logs of staff who work on more than one trial. Similarly trials should ensure that each site maintains a local training log, not least to integrate the logs of staff who work for more than one sponsor.

Training in this SOP will be in two stages. First, training in the principles of this SOP will take place during monthly meetings of the JSOPG. Second, training in using this SOP in practice will take the form of regular supervision by one of the authors. The trainer and trainee will sign the Training Log (Appendix 8) to confirm that training is complete.

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The TM/TC should undertake project management training for clinical trials. The TDM and clerical staff should receive training in project management principles at an early stage in the project either from the TM/TC or course attendance.

Swansea University provide PRINCE2 and project management courses.

8   References

1. PRINCE2 Managing Successful Projects with PRINCE2 Manual, 2009, Office of Government Commerce, The Stationery Office.

2. PRINCE2 website – http://www.prince2.com

9   Related SOPs

WWORTH SOP1b Document Control
WWORTH SOP07 Trial Closure
WWORTH SOP08 Archiving
WWORTH SOP09 User Inclusion
WWORTH SOP13 Protocol Development
WWORTH SOP14 Ethics Approval
WWORTH SOP15 MHRA Approval
WWORTH SOP17 Monitoring
WWORTH SOP18a Quality Management
WWORTH SOP29 Trial Reporting
WWORTH SOP31 Sponsorship and Adoption
WWORTH SOP32 Detecting and Managing Misconduct, Serious Breaches and Deviations from GCP/Protocol

10   Appendices

Appendix 1   - Example of Risk Log
Appendix 2   - Example of Gantt chart
Appendix 3   - Example of a project management structure
Appendix 4   - Proforma for Product Description
Appendix 5   - Example of Product Description for a final report
Appendix 6   - Example of Issue Log
Appendix 7   - Proforma for reporting to TMG

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Appendix 1: Example of a Risk Log

Risk ID Code	Risk Category	Author	Date identified	Date updated	Risk Description	Impact	Impact (VL / L / M / H / VH)	Countermeasures	Likeli hood (VL / L / M / H / VH)	Monitoring	Risk Owner	Current Status - Following last Review
1	Collaborators	ABC	05/12/2007	10/03/2008	Failure of collaborators to provide work that they have been contracted for	Missing data	H	Letters of agreement to be signed by all collaborators	VL	Regular monitoring of study progress through monthly project meetings	CI	No change
2	Research	XYZ	05/12/2007	10/03/2008	Failure to recruit the proposed number of trial centres	Reduced number of patients in study	H	Additional sites will be selected as back-up sites to replace any not wishing to participate	VL	Regular monitoring of study progress through monthly project meetings	CI	Reducing
3	HR issues	DEF	05/12/2007	10/03/2008	Retention of staff in the 40 trial centres	Reduce number of patients recruited and data collection	L	Ongoing liaisons with study centres to ensure that staff are retained for the duration of the study	L	Regular contact and liaison with trial centres	CI	No change

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Appendix 2: Example of a Gantt chart

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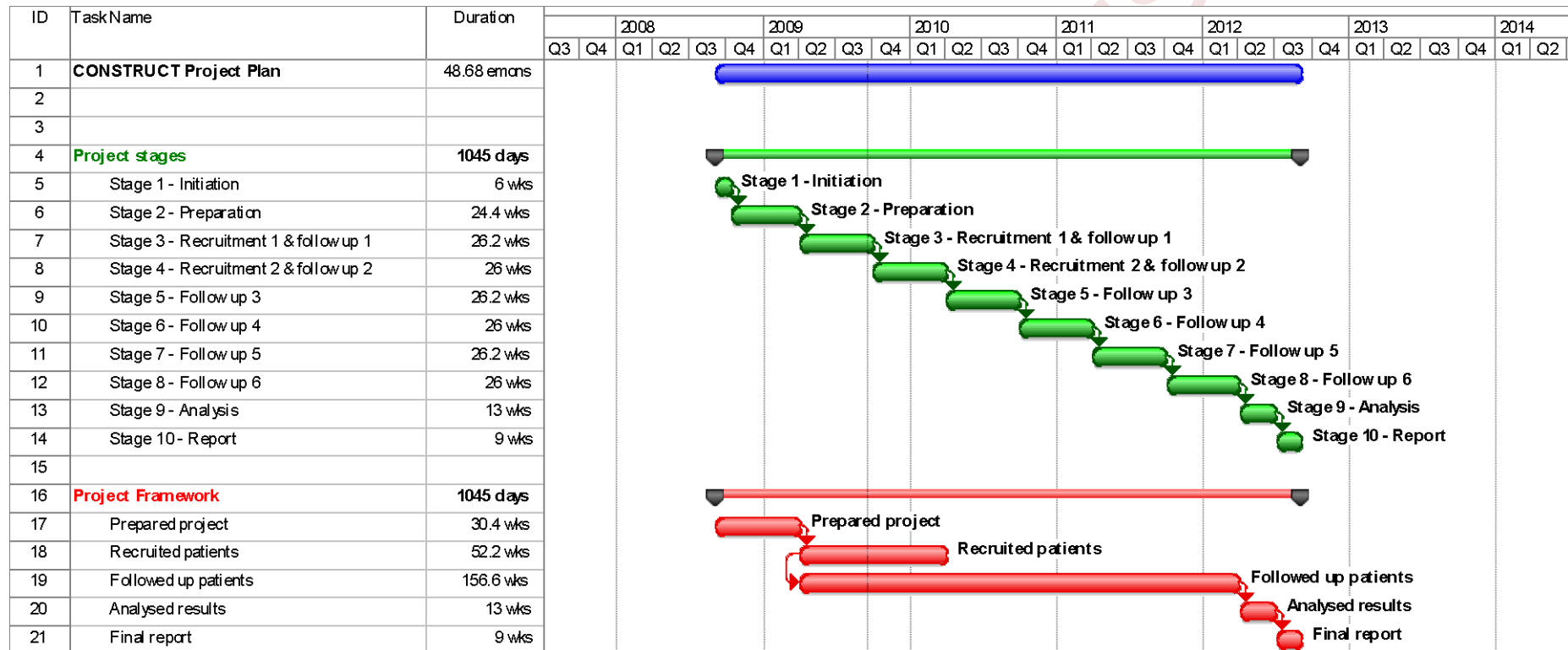
Appendix 3: Example of a Project Management Structure

XXX Project Management Structure

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Appendix 4: Example proforma of Product Description

Details of Product Description (PD)	
Author	
Document Ref	
Version number	
Date	

Revision History			
Date	**Summary of changes**	**Author**	**Version**

Distribution details		
Date	**Version circulated**	**Distribution list**

Approvals (this document requires the following approvals:				
Document date	**Version**	**Name of signatory**	**Role**	**Date of signature**

Title	*Name by which product is known*
Purpose	*Why is the product required?*
Scope	*The intended coverage of the product.*
Composition/Contents	*List of the parts of the product, e.g. if product were a document, this would be a list of the expected chapters or sections.*
Derivation	*What are the inputs/sources from which the product is derived, i.e. where has the product/outcome come from? Either a document or another function.*
Responsibility allocated to:	*Who is responsible for preparing the completed product?*
Format & presentation	*Standard appearance to which the product must conform.*

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Quality criteria	*To what standard(s) does the product need to conform and how will those inspecting/reviewing the outcome know the standard (quality measures) have been met? This may be by reference to one or more common standards documented elsewhere or perhaps fully explaining the characteristics to be applied.*
Quality check method	*The process for checking eg test, review, inspection, to be used to check the quality of functionality of the product.*
Quality tolerance	*Details of any range in the quality criteria within which the product would be acceptable. This may be accompanied by a series of time periods during which the product quality is required to improve so that it remains within tolerance.*
Quality check skills required	*Either identification of the people who are to check the quality, an indication of the skills required to do so, or a pointer to which areas should supply the checking resources.*

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Appendix 5 Example of Product Description for a Final Report

(page 1 of 2)

Details of Product Description (PD)	
Product name	xxxxx Final Report
PD Author(s)	xxxx
PD Owner	xxxx
PD File name	xxxx
PD File type	MS Word 2003

Revision History			
Date	**Summary of changes**	**Author**	**Version**
10/08/2009	**Creation of draft report**	**XYZ**	**V1-0 10Aug2009**

Distribution details		
Date	**Version circulated**	**Distribution list**
11/08/2009	**V1-0 10Aug2009**	**TMG**

Approvals (this document requires the following approvals:				
Document date	**Version**	**Name of signatory**	**Role**	**Date of signature**
10Aug2009	**V1-0**	**ABC**	**Chief Investigator**	**12/08/2009**

Title	Final Report
Purpose	To ensure that the production of the Final Report fulfils the agreement with [funder] to conduct and report on the research project xxxxxx.
Scope	The Final Report will include all appropriate information from the study required to provide the funding body with the evidence about the two drugs that are being compared.

Composition/Contents	**Title page**
	List of abbreviations/glossary
	Executive summary
	    (no more than 1500 words, appear at front of report as unnumbered `section, no references, figures or tables)
	Introduction
	    (including scientific background and explanation of rationale)
	Methods
	    (including info about participants, interventions, objectives, outcomes, sample size, randomisation, blinding, statistical methods, summary of any changes to the project protocol)
	        Section to include quantitative, qualitative, economics, IT and routine data methods

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	Results
	    (including participant flow, recruitment, baseline data, numbers analysed, outcomes and estimation, ancillary analyses, adverse events)
	    Section to include quantitative, qualitative, economics, IT and routine data results
	Discussion
	    (including interpretation, generalisability, overall evidence)
	Conclusions
	    (including implications of healthcare, recommendations for research
	Acknowledgments
	References
	Appendices		

Derivation	[funder] template Quantitative data analysis Qualitative data analysis	Economics data analysis IT infrastructure	Routine data analysis Study protocol
Responsibility allocated to:	Research team. Contributors to be agreed.		
Format and Presentation	1) One electronic version of final report, either CD-ROM (with paper copy) or emailed simultaneously with paper copy. 2) One A4 size, unbound, paper copy of the final report, typed in 11 point, Times New Roman font. -1.5 line spacing throughout, (including within tables) - each page numbered - main text of report should be no than 50,000 words (provide total word count) - title page should give details of any authors' competing interests. If none, state *Declared competing interests of authors: none.* - adequate margins (minimum 25mm).		
Quality criteria	Must cover all items defined in Composition 1. Document conforms to [funder] document template & style 2. Document contains all sections identified in product description composition. 3. Document is free from typographic errors. 4. Document fulfils its product description. 5. Document is relevant, unambiguous and easily understood. 6. Document review date has been set. 7. Document conforms to study xxxxx quality assurance plan. 8. Roles and responsibilities clearly and unambiguously defined		
Quality check method	1) Internal review by research team 2) Proof reading by word processing software and research team 3) Check against [funder] requirements		
Quality tolerance	None identified		
Quality check skills required	Knowledge of the project. All members of the research team as appropriate		

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Appendix 6: Example of an Issue Log

Issue ID	Issue Type	Author	Identified	Last updated	Description (include references to supporting documentation)	Priority	Action	Owner	Current Status
1	Funding	ABC	01/09/2008	06/04/2009	Drug costs	Medium	XXX emailed companies. Await outcome. 06/04/09 -YYY have requested study safety data. Advice to be sought from HTA.	CI	Resolved
2	Methodology	ABC	09/07/2008	06/08/2009	Problem of coping with first language not English in some centres - eg Inner City.	Low	7th May 2009 - Responsibility delegated to CLRNs. 06/08/09 issue to be classified as 'hibernating'.	CI	Hibernating
3	Trial Outcomes	GHI	11/06/2009	06/08/2009	Feasibility study – implications of low recruitment numbers	High	Review numbers next month.	GHI	Resolved

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Appendix 7: Example proforma for reporting to TMG

TRIAL UPDATE REPORT	
Project name	
Period covered	[Insert date of period covered]
Prepared for TMG meeting on	[Insert date]
Section of trial covered by this report	[Insert as appropriate eg. Health Economics]
Author	[Insert author]
Date	[Insert date prepared]

Summary of progress	
Follow up comments from previous reports	
Work completed during period	
Work in progress	
Work planned for next period	
Risks already identified	[Comments on previous risks]
Risks identified in this period	
Issues already identified	[Comments on previous issues]
Issues identified in this period	
Decisions made at operational group meetings to be brought to TMG	
Points for discussion at TMG	
Outcome of discussion at TMG	