Dorset County Hospital NHS Foundation Trust

Set Up of a Research Project at DCHFT

Policy Title	*Set Up of a Research Project at DCHFT*		
Policy Number	**RESSOP009**	**Policy Version Number**	**4.0**
Applicable to	*All staff undertaking research activity on behalf of the Trust.* *The Research & Innovation department.*		
Aim of the Policy	*To provide a policy on the set up of research projects at DCHFT.*		
Next Review Due Date	*19/02/2027*		
Author/ Reviewer	*Anthony Homer, Research Governance & Quality Lead*		
Policy Sponsor	*Sarah Doyle, Joint Head of Research*		
Expert Group	*R&I Business & Quality Group*		
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1. Quick Reference Guide

The Quick Reference Guides for this SOP are:

The Feasibility & Assessment Workflow

The Project Set Up Workflow

The Local Information Pack Tracking Workflow

The Amendment Workflow

All available on the edge database (Local Portfolio Management System). In order to gain access to the edge database, please contact research@dchft.nhs.uk.

Introduction

2.1 Research conducted within the Trust is monitored and supported by the Research & Innovation department.

2.2 Research can be conducted by any staff member of the Trust with approval and oversight from the Research & Innovation department.

2.3 This Standard Operating Procedure (SOP) outlines the process for setting up and maintaining research projects within the Trust.

2.4 Note that this policy does not relate to designing research projects, but to setting up and maintaining a research project that is designed and has all appropriate regulatory approvals.

2.5 The Health Research Authority (HRA) broadly defines research set up into; Assess, Arrange and Confirm. This SOP follows local definitions so as to be easily understandable to delivery staff, but is written to comply to the overarching guidance of the HRA.

2. Aim and Objectives of the Policy

3.1 To provide operational guidance on how to set up and maintain research projects within the Trust.

3.2 To provide a framework against which all research projects can be conducted within the Trust to the same standard.

3. Who is the Policy for

4.1 All Trust staff who seek to undertake research as defined by the HRA (for guidance see their decision tool).

4.2 The Research & Innovation department.

4. Definitions, Legislation, Policies, Guidelines and References

4.1. Definitions

Research – Research in the context of this SOP refers only to research as defined by the Health Research Authority (HRA) using their decision tool.

4.2. Guidelines

5. Equality Impact Assessment

6.1 A short statement summarising the assessment sheet, the completed Equality Impact and Compliance Assessment (Ref 1772) for the policy, is attached as Appendix A.

6.2 For more information, read the Equality Policy EM67 (Ref 1772)

6. Data Protection Impact Assessment

7.1 Please refer to the Data Protection and Confidentiality Policy (Ref 1751)

7.2 If the policy is exempt it should be documented here, otherwise read the Data Protection Impact Assessment (Ref1751) and complete the Data Protection Impact Assessment (DPIA) Screening Questionnaire (Ref 1751) and attach as Appendix B (a blank version has already been attached below for you).

7.3 The Information Governance Officer is happy to assist with the completion of the Screening Questionnaire if required. If a full DPIA is required, it should be completed in consultation with the Information Governance Officer and attached as appendix B.

7. Stakeholders and Consultation

8.1 Individuals from the Research Support Staff and Research Nursing teams were consulted in the course of the development of this SOP.

8.2 Individuals from other Trusts and Regulatory Agencies, such as but not limited to; University Hospitals Dorset, University Hospitals Southampton, the HRA, and the Medicines and Healthcare products Regulatory Agency (MHRA) were consulted in the course of the development of this SOP.

8. Roles and Responsibilities

9.1 Principal Investigators - are responsible for the overall set up, maintenance, and conduct of the study according to Good Clinical Practice (GCP), local and national policies, procedures and regulatory requirements.

9.2 Head of Research - Overall responsibility for the Research & Innovation Department.

9.3 Research Governance & Quality Manager (RGM) - local subject matter expert on GCP and research regulations; review and approval of local procedures and deviations; alongside the Lead Research Nurse (LRN) for the sign off and escalation of feasibility.

9.4 LRN; alongside the RGM for sign off and escalation of feasibility, for clinical team standards and support for projects when supplied by the Research & Innovation team.

9.5 Research Support Staff; for following this SOP and escalating deviations to the RGM

9.6 All staff involved in research; for following this SOP, identifying training needs and escalating to the RGM.

9. Dissemination

10.1 This approved policy will be sent by email to all current members of the Research & Innovation department, with a link to the published policy.

10.2 This approved policy will be uploaded to the Trust Policies and Clinical Guidance database and published via the Trust StaffNet.

10. Training and Implementation

11.1 All staff in the Research & Innovation department receive GCP training.

11.2 All relevant staff involved in the Research & Innovation department will be assessed according to the Quick Reference Guide of this policy and signed off by another member of the Research & Innovation department.

11.3 All staff working in the Trust attend Trust Mandatory Training.

11.4 All staff involved in the set up and maintenance of research projects receive proportionate GCP training.

11. Monitoring and Reviewing Arrangements

12.1 To be reviewed one year (12 months) after initial approval.

12. Policy Approval

13.1 The policy has been approved in accordance with the Policy for the Management of Policies and Guidance (Ref 1126) and Procedure for the Development of Policies (Ref 1909).

13.2 This policy has been reviewed by the R&I Business & Quality Group.

13. Procedure for the Identification of a Research Project.

13.1. Research projects can be found in several ways, such as:

- Email seeking expressions of interest from the Clinical Research Network.
- An individual finding out about a project running in other Trusts.
- Word of mouth about a new project being designed elsewhere.
- Searching for a project via the internet, for example: clinicaltrials.gov; cancerresearchuk.org.
- Recommendation by research staff.
- Being approached by the research sponsor to request involvement.

Upon identifying a research project, the Research & Innovation team should be contacted at the earliest opportunity via the research@dchft.nhs.uk single point of contact email address.

For convenience, in all sections, “the sponsor” refers to any contact for the research project itself including CROs, Co-Sponsors, and other delegated support for the Sponsor; “the investigator” refers to the individual with the lead interest in the project on site.

13.2. Research projects may require official documents, such as an Expression of Interest form, or Confidentiality Agreement, to be signed before sharing any information. In this case;

13.3 Confidentiality Agreements must be sent to research@dchft.nhs.uk for review prior to signature by an authorised person. This could be (in order of preference);

- the Research Governance & Quality Lead
- the Head of Research
- any other individual with delegated authority to sign off an agreement on behalf of the Trust.

13.4 All information supplied on an Expression of Interest form should be accurate; data and support in completion can be obtained via the research@dchft.nhs.uk email address if requested. Usual information requested includes but is not limited to an estimate of patient population, current research activity in the area and potential investigator.

13.5 If an estimate of how many participants could be recruited is requested, it is recommended the investigator follow the following formula;

Number of participants with the relevant condition seen in the Trust,
Halved to represent the number lost due to ineligibility,
Halved again to represent number of declines to participate.

Please note this is a recommendation only; in the event that there is unlikely to be as many participants lost due to ineligibility or declines to participate, this should be adjusted, and the reason for deviation from this formula noted, i.e. “simple eligibility criteria” or “highly engaged participant population”.

13.6 No patient identifiable information may be accessed by or sent to any individual outside of the direct clinical care team at this stage, except where there is an active research portfolio already concerning the area of research. Any perceived requirement for this information to be shared outside of the direct clinical care team should be raised with the research@dchft.nhs.uk email.

For avoidance of doubt, this includes members of the Research & Innovation department, who are only considered members of the direct clinical care team once there is an active research portfolio in the area of research.

13.7. The research@dchft.nhs.uk email address should be cc’d on all communication with the sponsor.

13.8. When requesting documents from the sponsor, the following documents should be requested for use during the feasibility assessment of the project:

1. The protocol of the project.

2. The IRAS (Integrated Research Application System) form of the project.
3. The costing up of the project (e.g. Commercial Costing Template, Schedule of Events Cost Attribution Template)
4. The agreement document for the project (e.g. Contract, Organisation Information Document).

Other documents can be requested at this stage if the full Local Information Pack is available.

13.9 The "Date Site Invited" is the first response Dorset County Hospital receives from the Sponsor inviting the hospital to consider becoming a site. For avoidance of doubt:

1. An expression of interest is the Trust requesting consideration by the Sponsor.
2. A positive response to that expression of interest is the Sponsor inviting the Trust to consider being a site, thus the date site invited.

14. Procedure for the Feasibility Assessment of a Research Project

14.1. The Research & Innovation department will usually support an identified Principal Investigator in the feasibility assessment. Wherever possible, a co or sub-investigator should be identified for cover purposes.

The Feasibility Assessment procedure is conducted according to the Feasibility Assessment Workflow on edge. It is recommended that the Local Information Pack Tracker Workflow is also added at this stage, and any documents received noted on it. Access to edge can be requested by the research@dchft.nhs.uk email.

The Feasibility Assessment is recorded on the Study Planner. The Study Planner is an active document and does not need to be complete for a study to be considered feasible to take into set up. Access to this form can be requested via the research@dchft.nhs.uk email.

The LRN works with the delivery teams to ensure prompt and timely feasibility review, and will agree with the sponsor a suitable date for the commencement of set up activities. This process is reviewed through weekly Studies In Set Up (SISU) Meetings amongst the management team, and Portfolio Review meetings within individual Portfolios.

In the event no team is available to review the feasibility of delivery promptly, this should be communicated to the Sponsor, indicating that we are unable to identify a suitable date to commence set up activity, and therefore are unable to act as a site at this time.

15. Procedure for the Set Up of Research Projects

15.1 Once a date is agreed with the sponsor by the delivery team as to when set up activities should commence, the Research Department have 60 days to complete set up activity.

The Research & Innovation department will usually support an investigator in setting up a research project.

Set up of a research project is conducted according to the Project Set Up Workflow on edge.

All members of staff who are consenting in the project should have Good Clinical Practice (GCP) certificates valid within 2 years.

The following actions are listed in detail in the edge workflow;

15.2 Creation of an Investigator's Site File (ISF)

An ISF should be set up in line with the sponsor's requirements; electronic site files can be stored on edge. Where the sponsor states local procedure should be followed, the local Work Instruction for the set up of an Investigators Site File should be followed. This can be obtained by contacting research@dchft.nhs.uk.

15.3 Creation of edge entities, cost templates and other metrics

The Research & Innovation support staff will create edge entities (data entries), cost templates (for tracking costs) and keep the edge instance of the project up to date. The work instruction for creation of a project on edge shows how new projects can be created. All users involved in a research project should have an edge user account; the work instruction for management of the organisation has a section on creating user accounts. Edge entities include entities specifically for the purposes of highlighting data protection concerns, finance and storage arrangements.

15.4 Preparation for Confirmation of Capacity & Capability (C&C)

Confirmation of C&C lets the sponsor of the project know that the research project is set up and prepared to recruit. It may be that certain elements of preparation, the sponsor has their own policy on how to process, and this should always be raised with the RGM via the workflow on edge.

Otherwise, all activities should be completed in preparation for C&C, including but not limited to;

- All access to databases internal and external arranged
- All staff involved in the project on edge and with proportionate GCP training for their activities
- Completed delegation log
- A signed PI Declaration should be obtained (if the sponsor's contract doesn't include one, a local copy is kept as a quality form).
- Where possible, a potentially eligible participant or participants should be confirmed to be available to approach by the direct clinical care team. NOTE: at this stage the Research & Innovation department should still not have access to patient identifiable information, and any potentially eligible participants should not be provided with study documentation.
- For the purposes of contracting, the following should be identified clearly on the edge workflow;

Whether the project;

- requires access to patient records prior to consent by anyone other than the direct clinical care team (IRAS)
- requires representatives of the sponsor to be given access to DPR for monitoring purposes (Protocol & Sponsor information)
- requires the transfer of anonymised imaging scans (IRAS & Protocol)
- requires the transfer of samples to another site (and whether they are pre-existing or taken in the course of the project).

15.5 A process summary sheet (example – one page) should be drafted (where necessary, i.e. not covered in the Protocol, where deviating from local procedure) for the following research project procedures (for example);
- Local storage of samples, when the samples will be sent, who locally will send them
- Local invoicing of project income
- Local recruitment process (see patient trial journey, which may be adapted for use on a project)
- Local maintenance of consumables (such as needles, cotton buds, etc.)
- Local storage of medicines

These summary sheets should be signed off by the Research Governance Manager and saved in the study specific area of the research study, so that a process can be maintained and handed over to new staff. Note that sign off may occur electronically by email.

15.6 The Research Governance & Quality Lead should arrange the distribution of finances with the R&I department's Management Accountant and the Research & Innovation Support Team.

15.7. The Research Governance & Quality Lead must review & localize the agreement documents according to the national template, local work instruction and guidelines.

15.8 Site Initiation is is the process by which the sponsor received assurance that the Principal Investigator and support staff are trained, understand the protocol and ready to commence the study. This could take the form of a specific meeting or Site Initiation Visit (SIV) or happen naturally as a part of the set up process. Wherever possible, this should be arranged prior to the exchanging of contracts, if it involves training, or provision of material crucial to set up. There are sometimes training and attendance records that the sponsor keeps for the purpose of quality assurance.

15.9. The Study Planner must go to the RGQL and LRN for review & approval. Both will identify any further approvals required, escalating studies with significant financial risk as appropriate.

This must be done with the signed and completed study planner which should capture the following:

1. The overall cost of running the project for the Trust, including in staff time and material resources.
2. The overall clinical benefit (including potential benefit) of the research project.

3. The expected target (see 13.5) and any potential difficulties in recruitment.
4. Any risks identified in the protocol as applicable to the participants in the study, any risk-mitigating actions specified in the protocol, and the investigator's opinion on whether further actions are required to further mitigate the risk.
5. The overall availability of staff to contribute to the project, including Research & Innovation staff.
   (Staff outside of the Research & Innovation team are expected to gain approval from their line manager for involvement in a research project).
6. The GCP training requirements and status of all staff involved in the research.
7. Any requirements for space (clinic space, etc).
   (Written approval from the local manager of the clinic space is expected where needed).
8. The amount of money coming into the Trust directly from the Sponsor, and its distribution (as appropriate).
9. Any involvement from imaging, including transfer of existing images should be highlighted.
   (All research requiring Imaging involvement needs approval from the local IRMER expert).
10. Any involvement from Pharmacy and any need for sampling should be highlighted.
11. Signature from the investigator.

15.10 The Research Governance Manager will, once the workflow has been completed as actioned or unable to action due to sponsor requirement, and once the study planner has been completed, issue the contract for signature.

In some cases, set up is required to be expedited (for instance, due to Urgent Public Health status) in which case there may be elements of set up that are delayed until after contract is signed, but the workflow must reflect this and the study planner must be complete and signed.

15.11. Once the contract is signed by both Trust and Sponsor, recruitment can commence **on confirmation from the sponsor.** This is referred to as "Green light" to recruit, and may be a formal process or informal email, dependent on the sponsors requirements.

C&C should be issued on the same day of the last signature (Trust Signature) of the contract. In the event that this was not possible (due to set up activities being outstanding due to sponsor requirement, or Urgent Public Health status, or other contracting delays) the Research Project Manager should document this via the edge notes & workflow.

Appendix A

EQUALITY IMPACT AND COMPLIANCE ASSESSMENT

1. General	
Title of document	Set Up & Maintenance of a Research Project at DCHFT

Purpose of document	To lay out the process for set up & maintenance of a research project.
Intended scope	All staff undertaking research activity on behalf of the Trust under the oversight of the Research & Innovation department. The Research & Innovation department.

2. Consultation	
Which groups/associations/bodies or individuals were consulted in the formulation of this document?	Members of the R&I Team HRA & MHRA (loosely) Other Trust organisations.
What was the impact of any feedback on the document?	Changes to presentation and some inclusion of information.
Who was involved in the approval of the final document?	R&I Business & Quality Group
Any other comments to record?	

3. Equality Impact Assessment	
Does the document unfairly affect certain staff or groups of staff? If so, please state how this is justified.	No, the document applies to all staff that conduct research and doesn't affect them.
What measures are proposed to address any inequity?	N/A
Can the document be made available in alternative format or in translation?	(?) is this standard

4. Compliance Assessment	
Does the document comply with relevant employment legislation? **Please specify.**	N/A

5. Document assessed by:	
Name	Anthony Homer
Post Title/ Position	Research Governance Manager
Date	17th May 2021

Appendix B

Data Protection Impact Assessment (DPIA) Screening Questionnaire

Project/Policy/Procedure Title: Set Up & Maintenance of a Research Project at DCHFT

Project Lead: Anthony Homer
Date: 17th May 2021

Question		Yes	No	Unsure	Comments
1	Are privacy-intrusive[1] technologies being used?		*		Research may be conducted that involves technologies that fit this definition which will be escalated as appropriate via the edge data protection entity.
2	Are new and untested technologies being used?		*		Research may be conducted involving new and untested technologies, which will be escalated appropriately. This SOP is generic, and does not.
3	Are the purposes of data processing unclear?		*		
4	What is the lawful basis for processing data?		*		This SOP involves no processing of identifiable data in of itself; at no point during the set up process should anyone other than the direct clinical care team have access to patient identifiable information.
5	Are new or substantially different identification authentication requirements needed?		*		
6	Will there be a significant amount of new data about each person, or a significant change in the current data-holdings?		*		
7	Will there be new data about a significant number of people?		*		
8	Will there be a new link of personal data with another data-holding?		*		
9	Are the data collection procedures new, changed, unclear or intrusive?		*		
10	Will there be a new or changed data quality process?		*		
11	Will there be new or changed data security arrangements?		*		

[1] Intrusion can come in the form of collection of excessive personal information, disclosure of personal information without consent and misuse of such information. It can include the collection of information through surveillance or monitoring of how people act in public or private spaces and through the monitoring of communications whether by post, phone or online and extends to monitoring the records of senders and recipients as well as the content of messages.

12	Are there new or changed data access or disclosure arrangements?		*		
13	Are there new or changed data retention arrangements?		*		
14	Has any external data sharing been identified on the departments data flow map?		*		Not related to this SOP.
15	Is the personal data likely to raise privacy concerns with the individuals? e.g. health records, criminal records		*		
16	Is there any use of highly sensitive or biometric data? e.g. protected characteristics or finger print recognition		*		
17	Will personal data be disclosed to organisations or people who have not previously had access to the data?		*		Not as part of this SOP.
18	Will data collection and processing result in automated decision making which will have a significant impact on the individuals concerned?		*		
19	Will individuals be compelled to provide information about themselves?		*		
20	Is there a contract or data sharing agreement in place with all third parties?		*		Not as a part of this SOP, although this SOP covers contracting with external organisations.

If you have answered 'Yes' or 'Unsure' to any of the above, please consult with the Information Governance and Data Protection Officer. You may need to complete the full DPIA.

If all answers are 'No' or the Information Governance and Data Protection Officer has been consulted and approves, this Screening Questionnaire can be signed off by the Project Lead and responsible Information Asset Owner.

Name	**Job Title**	**Date**
Anthony Homer	Research Governance Manager	17th May 2021