1. Contents:

2. Changes from Previous Versions

2.1. This Standard Operating Procedure (SOP) is the first to have its exact name and reference, it has been developed as part of a total re-structure of past SOPs, including reviewing what the SOPs cover, therefore this SOP has no named previous versions.

3. Purpose:

3.1. The purpose of this SOP is to outline the process of applying for, processing, reviewing, and obtaining sponsorship from Dorset County Hospital for the conduct of a research study. This SOP should outline responsibilities, processes, and actions to take in order to prepare and apply for Dorset County to sponsor a research study.

4. Scope:

4.1. This SOP is limited to the process for obtaining sponsorship only. A full list of definitions can be found at point 7 of this SOP, however for the avoidance of doubt;

4.1.1. It should be noted that sponsorship in terms of a research project involves taking ultimate responsibility for the initiation, management and arranging of the financing of the research, and does not constitute an agreement to finance the research study.

4.1.2. It should be noted that an agreement of sponsorship does not allow any prospective researcher to begin recruiting participants on site at Dorset County Hospital, and once sponsorship is obtained a feasibility process would have to be

undertaken, although it is presumed the process would be expedited where the teams involved were involved in the design of the study.

4.1.3. It should be noted that for studies that require NHS REC (Research Ethics Committee) favourable opinion and HRA (Health Research Authority) approval, confirmation of sponsorship should occur prior to these applications, and changes requested at HRA and REC should take priority if they conflict with changes requested by the Sponsorship Committee.

5. Responsibilities:

5.1. Applicant/Researcher

5.1.1. Responsible for identifying, engaging and/or taking on the role of Chief Investigator, Principal Investigator(s) (if applicable) and any sites likely to be involved.

5.2. Chief Investigator (CI)

5.2.1. Responsible for the overall conduct of the study as a whole.

5.2.2. Responsible for the design of the protocol and all other study-specific documentation

5.2.3. Responsible for ensuring all documents are available for the Sponsorship Committee

5.2.4. Responsible for the IRAS (Integrated Research Approvals Service) applications and communication with the NHS REC service post-confirmation of sponsorship.

5.2.5. Responsible for the suitability of any individuals responsibility is delegated to (i.e. Principal Investigators)

5.3. The Head of Research (HoD)

5.3.1. Responsible for leading the department in promoting use of and conformance to the SOP.

5.3.2. Responsible for providing all necessary tools reasonably required to follow the SOP.

5.4. The Research Governance & Quality Lead (RGL)

5.4.1. Responsible for keeping this SOP and the associated forms in conformance with the latest relevant laws, enactments and guidance from the relevant authorities.
5.4.2. Responsible for the writing, updating and maintenance of the SOP.
5.4.3. Responsible for ensuring and tracking compliance to the SOP.
5.4.4. Responsible for organizing & chairing the Sponsorship Committee.

5.5. The Lead Research Nurses (LRN(s))

5.5.1. Responsible for ensuring clinical conformance of the SOP.
5.5.2. Responsible for the promotion, use of and conformance to the SOP.

5.6. The Principal Investigator (PI(s))

5.6.1. Responsible for the conduct of the study on site (as applicable)

6. Procedure:

6.1. Identification of a potential area for research ("idea" phase)

6.1.1. The Applicant/Researcher is encouraged to contact the Research department's generic email research@dchft.nhs.uk at the earliest opportunity after having a research idea, so as to ensure involvement and engagement at an early stage.
6.1.2. The Research Governance & Quality Lead will, as applicable, advise on what approvals the research idea would, in the form proposed, require, and notify the Head of Department of a potential research project.
6.1.3. The Head of Department will advise and aid the Applicant/Researcher on the design of the study, the funding routes available, and support the Applicant/Researcher generally in undertaking these procedures, with appropriate guidance from the Research Governance & Quality Lead.
6.1.4. The Head of Department and Research Governance & Quality Lead will advise the Applicant/Researcher on appropriate routes for Patient & Public Involvement in the design, justification, and conduct of the study.

6.2. Preparing for application to the Sponsorship Committee

6.2.1. The Applicant/Researcher will identify a potential appropriately qualified Chief Investigator, or take on the role themselves. It is expected but not necessary that the Applicant/Researcher in most cases at the Trust would be the Chief Investigator.

6.2.2. The Applicant/Researcher and Chief Investigator will design a research protocol/proposal outlining all appropriate activities as per the NIHR's and Lead Research Nurses' guidance, along with proportionate statistician and scientific support.

6.2.3. The Applicant/Researcher and Chief Investigator will identify how many sites will be required to obtain their proposed sample size and identify suitable sites to take part.

6.2.4. The Applicant/Researcher and Chief Investigator will identify potential Principal Investigator(s) at every site as applicable. It is expected but not necessary that in most cases the Chief Investigator will be the Principal Investigator at Dorset County Hospital, and in this case the Chief Investigator only need be named.

6.2.5. The Applicant/Researcher and Chief Investigator will source or obtain funding for the research protocol as applicable, it is requested that funding is obtained prior to application to the Sponsorship Committee where possible, it is expected that the researcher obtains agreements in principle, it is required that the Applicant/Researcher will have identified potential suitable income sources.

6.2.6. The Applicant/Researcher and Chief Investigator will, if not already done so, identify impartial peers who will not be involved in the study to review their research study design for validity, application, and appropriateness.

6.3. Applications to the Sponsorship Committee

6.3.1. Applications to the Sponsorship Committee are expected to be made to the Research Governance & Quality Lead in one email to the research generic email address research@dchft.nhs.uk, and should include:

(a) A research proposal/protocol
(b) Any peer reviews undertaken

(c) Any proof of early PPI involvement
(d) Any proof of funding obtained, agreed in principle, applied for or identified.
(e) A Good Clinical Practice (GCP) certificate and Research C.V. for the Chief Investigator and any identified Principal Investigators.
(f) Any supporting documents for the study which have been drafted prior to application to the Sponsorship Committee.

6.3.2. The RGL will arrange review by the Sponsorship Committee either by electronic review or, preferably, by arrangement of a meeting with documents to be distributed beforehand. The Sponsorship Committee must consist of, at a minimum:

(a) The Research Governance Lead or Head of Research
(b) A clinical representative from the Research Department (Lead Research Nurse or Research Nurse)
(c) The Clinical Director of Research or Medical Director
(d) A Patient Research Ambassador (PRA)
(e) A representative from the Finance Department

6.3.3. The Sponsorship Committee will review the research proposal or protocol based on their expertise, including but not exclusively any ethical concerns raised prior to formal HRA ethical review, the value of the study, the appropriate funding of the study, the degree of insurance or indemnity required to conduct the study. The Committee will establish a unanimous decision, an approval with conditions or advisories, or a rejection of sponsorship. In the event the Committee is unable to form a unanimous decision, the Committee will take a vote, mediated by the Research Governance & Quality Lead or Head of Research, whereby a majority will lead to approval or approval with conditions, subject to the power of veto granted to the Medical Director or Director of Research.

6.3.4. The Committee's decision will be conveyed by the RGL to the Applicant/Researcher and Chief Investigator within 10 working days of the committee's decision. the committees decision will either be:

(a) An approval, which will result in an issue of an agreement to be the sponsor from the RGL. The RGM will advise the recipient as per section 6.4. of this SOP.

(b) An approval with advisory, similar to the above but it is expected that the researcher take under consideration any advisory notices in the further design of their documentation.

(c) An approval pending conditions, the RGL will issue an email specifying certain conditions which require response, the recipient is expected to respond with evidence that the conditions have been met at which point the RGM will review independently and issue an approval based on the requirements set by the committee being met. It is not expected that the Committee would have to review the entire study again, but the Committee may request this in extenuating circumstances.

(d) A rejection of sponsorship proposal, the RGL will issue an email outlining the reasons the Committee rejected sponsorship for the study, dependent on the reasons for rejection, a revised application can be made at any future date and, if the reasons for rejection have been addressed, the study can be approved for sponsorship.

6.4. Post-sponsorship approvals

6.4.1. Once sponsorship approval has been obtained, the Chief Investigator will begin designing, with the support of the Head of Research, Research Governance Manager, any other investigators, and Patient & Public Involvement groups, designing their patient-facing documents if not done already.

6.4.2. The Chief Investigator will follow guidance from the Research Governance & Quality Lead and the relevant authorities on what documents are required for an application for HRA approval and/or NHS REC approval, and generate as necessary.

6.4.3. The Chief Investigator will finalize all finance and funding arrangements as necessary.

6.4.4. The Chief Investigator will submit an application using IRAS (Integrated Research Application System) with guidance from the RGL as necessary.

6.4.5. The Chief Investigator will maintain contact, or delegate responsibility for contacting appropriately, the NHS REC review of their study as applicable.

6.4.6. Once the research study has received all approvals, the study will be treated as per RESSOP009 – Set Up of a Research Project at DCHFT .

7. Abbreviations/Glossary

7.1. The following abbreviations and terms in the above SOP relate to their following definitions:

Term	Definition	Term	Definition
SOP	Standard Operating Procedure	CI	Chief Investigator
RGM	Research Governance Manager	IRAS	Integrated Research Application System
RN	Research Nurse	Management Team	Consisting of the HoD, Lead Research Nurses, and RGM
PI	Principal Investigator	HoD	The Head of Research & Innovation
Site	Dorset County Hospital NHS Foundation Trust & its satellites	Study	Any research study
LRN	Lead Research Nurse	Sponsor	The identified responsible organisation for a study

8. References

UK Policy Framework for Health and Social Care Research 2020
IRAS and supporting documents (myresearchproject.org.uk)