STANDARD OPERATING PROCEDURE

APPLYING FOR TRUST APPROVAL
S21

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DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless;

- A study specific SOP exists
- A departmental SOP dictates a different working practice

Once printed this is an uncontrolled document.

VERSION HISTORY LOG

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

VERSION	Date Implemented	Details of significant changes
1.1	3 January 2014	No significant changes. Corrected general typographical errors. Replaced “patient” with “participant” as per NIHR guidelines. Removed authorised signatory’s name from appendix 4 & 5. Removed “(for portfolio adopted studies only)” from the “Impact Form” row under “Feasibility Documents” in appendix 5.

CONTENTS

1. BACKGROUND

All research must be undertaken to high scientific and ethical standards and patients protected at all times. The standards set down in the Research Governance Framework 2001 (RGF), and as amended in the second edition of the framework 2005 state that any organisation providing care must be aware of, and give approval for all research activity involving patients, staff, organs, tissue or data, within that organisation. In cases where the Trust is also acting as sponsor, it is required to ensure compliance with the responsibilities of both Sponsor and of the Organisation providing care.

"Health and social care providers must have systems that ensure that they are aware of research conducted in or through their organisation, whether or not it is externally funded. No study should begin until a person with authority to do so has given written permission on behalf of the organisation." RGF paragraph 4.4

All research projects undertaken at the Royal Devon & Exeter NHS Foundation Trust (RDEFT) must obtain relevant approvals prior to commencement, notably a favourable Ethical opinion, Medicines and Healthcare products Regulatory Agency (MHRA) approval (if applicable) and NHS Trust Approval.

Governance arrangements for each project will differ. A risk assessment will be carried out for each project and the amount of governance assigned will be dependant on the outcome of the risk assessment and complexity of each project.

2. PURPOSE

All research projects carried out in section 5.1, must be registered with the Research & Development (R&D) Directorate and must not commence until a letter is issued confirming Trust Approval. A number of documents are required in order for approval to be provided. Even if regulatory approval(s) is given, the R&D Directorate may, on behalf of RDEFT, still refuse permission for a research project to be conducted within the Trust.

The registration process and final review is carried out by the R&D Department, with Trust Approval being granted by the Medical Director.

The purpose of this SOP is to provide guidance on obtaining Trust Approval from the Royal Devon & Exeter Hospital's (RD&E) R&D Department for research to take place within the Trust.

3. SCOPE

This SOP applies to all research proposed to be undertaken within the RD&E that involves patients, carers, service users, relatives, staff and honorary staff, patient data or tissues or utilising Trusts facilities or premises.

This SOP applies to all individuals with a role in NHS Trust Approval for research particularly the R&D Department and associated staff.

4. RESPONSIBILITIES

The RGF (paragraph 3.10.4) sets out the responsibilities of the R&D department on behalf of the Trust please see Appendix 1 for these responsibilities.

It is the responsibility of the Chief Investigator (CI) / Principal Investigator (PI) to submit documentation to ethics and the competent authority(s), and to obtain appropriate approvals from them.

It is the responsibility of the CI / PI to submit the necessary documents, and provide the necessary information to the R&D department so that they can conduct a review.

5. PROCEDURES

Different terms are used to describe when an NHS organisation gives consent for research activity including 'R&D Management Approval', 'NHS Trust Approval', 'NHS Permission' and 'Trust Approval'.

At RDEFT, the R&D department has the authority to review and recommend research activity on behalf of the Trust, however the authority to finally approve and sign off the research on behalf of the Trust remains with the Medical Director, therefore the term 'Trust Approval' is used in place of 'R&D Management Approval/NHS Trust Approval/NHS permissions'.

5.1 PROJECTS REQUIRING TRUST APPROVAL

Approval will be required from the RDEFT R&D department and the R&D departments for each health and social care organisation involved in research, if the research proposal is to involve any of the following:

- Patients and service users of the NHS;
- Participants identified as they are relatives or carers of NHS patients or service users;
- Patient data, organs and other bodily materials of living or deceased NHS patients;
- Foetal material and IVF involving NHS patients;
- Use of or potential access to NHS premises or facilities;
- NHS employees (whether as participants or research staff).

As a general rule, Trust Approval will always be required if NHS Research Ethics Committee (REC) approval is required. There may also be occasions where Trust Approval is required when REC approval is not required. A list of the types of projects requiring Trust Approval can be found in Appendix 3.

N.B. The RD&E is unable to sponsor or host Phase I Clinical Trials.

5.2 WHEN TO APPLY FOR TRUST APPROVAL

It is recommended that applications for Trust Approval, NHS REC and approval(s) from other regulatory bodies are submitted concurrently to prevent any delays.

The R&D office will not give approval unless and until all necessary approvals have been obtained – however submitting at the earliest opportunity will assist in preventing delays on other aspects of setting up the project.

5.3 APPLYING FOR TRUST APPROVAL – INTEGRATED RESEARCH APPLICATION SYSTEM (IRAS)

IRAS is a single online system for applying for a number of permissions and approvals for health and social care research in the UK. This system streamlines the process for seeking relevant approvals by ensuring that, as far as possible, details only need to be entered once for a single project and other forms then self-populate.

N.B. For studies that wish to have portfolio adoption, the CI must complete the portfolio adoption form which is available via IRAS.

The system allows the user to answer 'filter questions' which then generates the necessary forms required to obtain all relevant permissions and approvals including:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- **NHS R&D (such as RDEFT R&D)**
- Ministry of Justice (MOJ)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- National Information Governance Board (NIGB)
- NHS REC Committees
- Social Care Research Ethics Committees

All applications must be submitted through the IRAS system. The only exception to this are those studies which are not eligible for portfolio adoption and do not require NRES approval, for further guidance please contact R&D on 01392 406933.

Projects eligible for inclusion on the National Institute for Health Research (NIHR) portfolio must be completed in IRAS; after which they will be processed through the NIHR Coordinated System for gaining NHS Permissions Research and Development Management Information System (CSP RDMIS), (for studies being processed through CSP RDMIS please refer to the NIHR guidance).

5.4 USING THE IRAS SYSTEM

There is a vast amount of guidance available on how to use the IRAS system including:

- The Help page contains links to guidance, frequently asked questions (FAQs), a quick guide to using IRAS, an index to IRAS forms and questions, example applications forms and question-specific guidance.
- There is an e-learning module on the IRAS website which helps new users to familiarise themselves with using the system.
- Links to available guidance and the e-learning module is included in the References section below.

5.5 APPLYING FOR TRUST APPROVAL

For those studies that will be sponsored by RDEFT, steps 1-5 apply. For studies where RDEFT is only a participating site, PI's are required to follow steps 3-5.

For portfolio adopted research please follow the guidance provided on IRAS and CSP RDMIS.

Please note the document checklists provided in Appendices 5 & 6 are for guidance only and the actual documents required to apply for Trust approval will be proportionate to the type and risk rating of each project.

STEP 1. Initial Correspondence & Support

The RD&E R&D department may be contacted before a full application is submitted for help and support. R&D offers a range of support to researchers which includes, but is not limited to conducting scientific reviews, guidance on methodology, advice on portfolio eligibility and support to complete the IRAS forms.

The R&D Department can provide sponsorship on behalf of the Trust, if you require the RD&E to sponsor your study, please refer to the SOPs;

1. 'Application to the Trust for Sponsorship of a CTIMP' (R&D/CTIMP Sponsorship/S09).
2. 'Application to the Trust for Sponsorship of a Non-CTIMP' (R&D/Non-CTIMP Sponsorship/S48).

STEP 2. Is it research?

Unless a favourable ethical opinion has already been issued by an NHS REC, it may be necessary to consider if the proposal is 'research' as defined in the RGF by either contacting the R&D department or referring to the guidance on the ethics and/or RD Forum websites;

http://www.nres.nhs.uk/applications/guidance/research-guidance/?entryid62=66984
http://www.rdforum.nhs.uk/docs/categorising_projects_guidance.doc

If a proposal appears to be audit or service evaluation, then you will be advised of the route to follow within the Trust for approving such projects.

STEP 3. Complete applications IRAS

All required forms should be completed in IRAS which will include the NHS R&D and Site Specific Information (SSI) forms together with supporting documentation listed in the 'Applicant's Checklist' in IRAS. The forms must be ready for sign-off by the CI, Sponsor and any other required signatories as indicated by the system. This can be done either via electronic or wet ink signature.

If you want RDEFT to act as Sponsor (see R&D/CTIMP Sponsorship/S09) then an email request should be submitted to rde-tr.research@nhs.net .

STEP 4. Submission

Applications to all NHS R&D offices should be made concurrently with applications to the NHS REC (see R&D/Ethical Approval/S13) and, for Clinical Trials of Investigational Medicinal Products (CTIMPs) to the MHRA (see R&D/Applying for MHRA Approval/S54).

The documents to be submitted to the RDEFT R&D department will vary depending on the type of research being conducted. Appendices 4 & 5 provide guidance on the types of documents required, as listed in the IRAS 'Submission Checklists'. Not all of the documents included on the Submission Checklists may be applicable; however, any documents that have not been submitted will be requested and should be forwarded immediately to prevent delay in processing your application.

For a full list of required documentation for your research, please contact the R&D office on;

01392 403055 (Commercial Research)
01392 406933 (Non-Network Research)
01392 403042 (Network Research)

All documents must be submitted electronically either via email or through the CSP RDMIS/IRAS systems (for portfolio adopted studies). It is preferable that electronic signatures are used wherever possible; however wet ink signatures will also be accepted. Copies of wet ink signatures must be posted to;

R&D Department
Floor 3 Noy Scott House
RD&E Wonford
Barrack Road
Exeter, EX2 5DW

The names of the documents should be clear and indicative of their contents, as well as showing version numbers and dates (e.g. Trial Protocol v1.4 dated 20th July 2010).

STEP 5. Governance Review

Once the NHS R&D form, SSI form and required documents have been received (a valid application), the R&D Project Clock will commence. We aim to process applications as quickly as possible – however this may take longer depending on other regulatory approvals that are required e.g. National Research Ethics Service (NRES).

If there are any specific reasons why your application should be expedited, please let us know and we will try to accommodate this.

The Research Governance team will review the application and all documents that have been submitted. A Site Specific Assessment (SSA) will be done (this is a review of the suitability of the research team, the research site and facilities for a research project). In addition to specific checks that may be necessary depending on the nature of the research, the team will check that:

- All relevant approvals have been obtained or have been applied for;
- Necessary contractual arrangements are put in place;
- There are adequate resources to meet the standards set out in the RGF from commencement to completion of the research – including finance, staff and facilities capacity (Pharmacy, Radiology, Labs and other support departments);
- Allocation of responsibilities are agreed and documented;
- All research staff possess the necessary level of access (i.e. an Honorary Contract or Letter of Access) and are trained by education and experience for their role(s) in the research.

It may be necessary to arrange a short meeting with the CI/PI or delegated member of the research team to develop an accurate picture of the project costs and whether the funding will cover them.

N.B. For CTIMPS not sponsored by RDEFT, where there is a requirement to send/forward questionnaires directly from participant to a Trials Unit/Data Centre, the PI must inform the Sponsor that it is a requirement that a system is in place for reporting any AEs/SAEs that may be documented on the questionnaire to the PI based at RDEFT. For further information on the need for this requirement please visit the MHRA feedback page in the R&D section of IaN (http://ian.exe.nhs.uk/welcome/directorates/research-and-development/research-development/latest-news/mhra-inspection/).

STEP 6. Approval

Subject to all the relevant checks being satisfied, Trust Approval will be issued. Once approval is given, the research can proceed at the RD&E.

6. FURTHER READING

Department of Health (2001) *Research Governance Framework for Health and Social Care* Department of Health; London
Department of Health (2005) *Research Governance Framework for Health and Social Care (2nd Edition)* Department of Health; London
Integrated Research Application System (IRAS) - https://www.myresearchproject.org.uk/
National Research Ethics Service (NRES) - http://www.nres.nhs.uk/
NHS R&D Forum - http://www.rdforum.nhs.uk/

R&D/CTIMP Sponsorship/S09
R&D/Non-CTIMP Sponsorship/S48
R&D/Ethics Approval/S13
R&D/MHRA Approval/S54

APPENDIX 1 – DEFINITIONS

The RGF (paragraph 3.10.4) sets out the responsibilities of the R&D department on behalf of the Trust as follows:

- Retain responsibility for the quality of all aspects of participants' care, whether or not some aspects of the care are part of a research project;
- Maintain a record of all research undertaken through or within the Trust, including research that students undertake as part of their training;
- Ensure patients or users and carers have information on any research that may affect their care;
- Ensure legislation relating to research is followed within the Trust;
- Require that no research project involving human participants for whom the Trust is responsible (or their organs, tissue or data), begins until:
    a. A sponsor has confirmed it has taken responsibility;
    b. The proposed research has a favourable ethical opinion (and if the project is a Clinical Trial of an Investigational Medicinal Product (CTIMP), clinical trial authorisation);
    c. A person authorised to do so has given written permission on behalf of the Trust,
- Ensure written agreements are in place about responsibilities for all research involving an external partner, funder and/or sponsor, including agreement with the university or other employer on supervision of student research;
- Maintain links with clinical governance and/or best value processes;
- Ensure researchers with no contractual relationship with any NHS body, who are to interact with individuals in a way that directly affects the quality of their care, holds honorary NHS contracts or other modes of access, and that there is clear accountability and understanding of responsibilities for the conduct of the research;
- Put and keep in place systems to identify and learn from errors or failures associated with any research undertaken through or within the Trust;
- Ensure that significant lessons are learnt from errors or complaints and from internal enquiries are communicated to funders, sponsors and other partners;

- Ensure that adverse incidents in the context of research are reported to the appropriate bodies in line with standard procedures;
- Permits and assist with monitoring, audit or inspection by the relevant authorities.

APPENDIX 2 – ABBREVIATIONS

ARSAC	Administration of Radioactive Substances Advisory Committee
ATMP	Advanced Therapy Medicinal Product
CI	Chief Investigator
CiMD	Clinical investigation of a Medical Device
CSP	Coordinated Systems for gaining NHS Permissions
CTIMP	Clinical Trial of an Investigational Medicinal Product
GTAC	Gene Therapy Advisory Committee
IRAS	Integrated Research Application System
MA	Marketing Authorisation
mNCA	model Agreement for Non-Commercial research
mCTA	model Clinical Trial Agreement
MHRA	Medicines and Healthcare products Regulatory Agency
MOJ	Ministry of Justice
NIGB	National Information Governance Board
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
PI	Principal Investigator
PIC(s)	Participant Identification Centre(s)
R&D	Research & Development
RD&E	Royal Devon & Exeter
RDEFT	Royal Devon & Exeter NHS Foundation Trust
RDMIS	Research and Development Management Information System
REC	Research Ethics Committee
RGF	Research Governance Framework
SSA	Site Specific Assessment
SSI	Site Specific Information
SOP	Standard Operating Procedure

APPENDIX 3 – PROJECTS REQUIRING RDEFT TRUST APPROVAL

The following projects require the approval of the RD&E R&D Department:

Proposals defined as 'research' according to the definition in the RGF and which involve:

- Patients and service users of RDEFT;
- Participants identified as they are relatives or carers of RDEFT patients or service users;
- Patient data, organs and other bodily materials of living or deceased RDEFT patients;
- Foetal material and IVF involving RDEFT patients;
- Use of/or potential access to RDEFT premises or facilities;
- RDEFT employees (whether as participants or research staff).

Research satisfying any one or more of the above criteria includes:

- CTIMPs from Phase I-IV and post-marketing surveillance of Medicinal Products holding Marketing Authorisations (MA);
- Advanced Therapy Medicinal Product (ATMP) research[1];
- Clinical investigations of Medical Devices (CiMDs) which have not been CE-marked or are CE-marked and are being applied for a different therapeutic purpose;
- Clinical evaluations and post-marketing surveillance of Medical Devices which have been CE-marked and for which a favourable ethical opinion is required by an NHS Research Ethics Committee (REC);

[1] Advanced Therapy Medicinal Products (Advanced Therapies or ATMP's) are innovative, regenerative therapies which combine aspects of medicine, cell biology, science and engineering for the purpose of regenerating, repairing or replacing damaged tissue/cells. ATMP's include any of the following medicinal products for human use: (1) a gene therapy medicinal product, (2) a somatic cell therapy medicinal product, or (3) a tissue engineered product.

- Randomised controlled trials involving medical or surgical interventions;
- Observational research projects;
- Human tissue research;
- Other interventional research including imaging investigations, mental health investigations or therapies, physiological investigations, trials of products that defined as medicines for devices (e.g. nutritional), complementary or alternative therapy investigations;
- Gene or stem cell therapy research;
- Xenotransplantation research;
- Establishment of research databases and registries;
- Questionnaire-based research;
- Laboratory-based research.
- Participant Identification Centre(s) (PIC[s])[2]

APPENDIX 4 – DOCUMENT SUBMISSION CHECKLIST: CTIMPS

PLEASE NOTE THAT OTHER DOCUMENTS MAY BE REQUIRED ON A CASE-BY-CASE BASIS

Document Required in Application
IRAS Forms
R&D Form (Parts A-D) (signed/authorised pdf or hard copy) and XML file
Site-Specific Information Form (signed/authorised pdf or hard copy) and XML file
Protocol, Investigator Brochure & instructions for use *
Research protocol
Investigator's brochure / Summary of Product Characteristics
Summary, synopsis or diagram (flowchart) of protocol in non-technical language
Details of any Data Monitoring Committee
Participant Related Documentation **
Research participant information sheet (PIS) - local version
Research participant consent form - local version
Letters of invitation to participant - local version
GP/consultant information sheets or letters - local version
Sample diary card/participant card
Validated questionnaire
Non-validated questionnaire
Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script.
Feasibility Documents
Summary CV for Chief Investigator (CI)(signed and dated)
Summary CV for Principal Investigator (PI) (signed and dated)
Summary CV for local researchers and research nurses (signed and dated)
GCP for Chief Investigator (CI)(signed and dated)

[2] Participant Identification Centres (PICs) are organisations from which clinicians or clinical units refer potential participants to a research team based in another organisation. The PIC site is only responsible for the identification of potential participants who are subsequently invited to take part in research through a different site which takes on responsibility for seeking consent and undertaking research procedures. PICs can include research units undertaking support functions, such as project management, site monitoring, data analysis or report writing.

GCP for Principal Investigator (PI) (signed and dated)
GCP for local researchers and research nurses (signed and dated)
Evidence of insurance or indemnity (non-NHS sponsors only)
Draft Contract/Agreement ***
Letter from statistician
Letter from funder
Referees' or other scientific critique report
Impact Form
Documents required once available and prior to Trust Approval
Written final confirmation from the organisation(s) acting as sponsor
REC favourable opinion letter and all correspondence
Confirmation of REC favourable opinion for any substantial amendments
Confirmation of clinical trial authorisation from MHRA and all correspondence
Confirmation of authorisation from MHRA for any substantial amendments
Confirmation of any other regulatory approvals (e.g. NIGB) and all correspondence

N.B. The above checklist provides an overview of the types of documents that will be required for a CTIMP. The documents required by R&D will vary depending on whether the Trial is Sponsored by RDEFT, hosted by RDEFT or portfolio adopted.

For those Trials progressing through the CSP RDMIS system, please follow the document submission guidance on IRAS.

For further guidance please contact the R&D Office on the details given in section 5.5 (step 4).

Submission Notes

* Please send the most recent approved version(s). If there have been any changes to these documents after REC approval has been granted; we will require historical versions of these documents and copies of any ethical approvals pertaining to them.

** Please send the most recent approved version(s). If there have been any changes to these documents after REC approval has been granted; we will require historical versions of these documents and copies of any ethical approvals pertaining to them.

*** In the case of commercially sponsored Clinical Trials, the ABPI model Clinical Trial Agreement (mCTA) must be used without modification. Additional charges will be levied for seeking legal advice if modifications are proposed. For non-commercial sponsored Clinical Trials, the model Non-Commercial Agreement is preferred.

Contract Administrative Details

Organisation Legal Title	Royal Devon & Exeter NHS Foundation Trust
Organisation Legal Address	Royal Devon & Exeter NHS Foundation Trust RD&E Wonford Barrack Road Exeter EX2 5DW
Authorised Signatory for Commercial Contracts	Medical Director
Authorised Signatory for Non-Commercial Agreements	R&D Directorate Manager
Notices	R&D Directorate Manager Floor 3 Noy Scott House

	RD&E Wonford Barrack Road Exeter, EX2 5DW
Bank Details	This information is available upon request. Please include the following statement where bank details are requested: *"Royal Devon & Exeter NHS Foundation Trust will raise invoices upon notification from you and payment should be made according to invoice instructions."*

APPENDIX 5 – DOCUMENT SUBMISSION CHECKLIST: NON-CTIMPS

PLEASE NOTE THAT OTHER DOCUMENTS MAY BE REQUIRED ON A CASE-BY-CASE BASIS

Document Required in Application
IRAS Forms
R&D Form (Parts A-D) (signed/authorised pdf or hard copy) and XML file
Site-Specific Information Form (signed/authorised pdf or hard copy) and XML file
Protocol & instructions for use *
Research protocol
Instructions for use of medical device
Summary, synopsis or diagram (flowchart) of protocol in non-technical language
Participant Related Documentation **
Research participant information sheet (PIS) - local version
Research participant consent form - local version
Letters of invitation to participant - local version
GP/consultant information sheets or letters - local version
Interview schedules or topic guides for participants
Validated questionnaire
Non-validated questionnaire
Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script.
Feasibility Documents
Summary CV for Chief Investigator (CI)(signed and dated) ***
Summary CV for Principal Investigator (PI) (signed and dated)
Summary CV for local researchers and research nurses (signed and dated)
Evidence of insurance or indemnity (non-NHS sponsors only)
Draft Contract/Agreement ****
Letter from statistician
Letter from funder
Referees' or other scientific critique report
Impact Form
Documents required once available and prior to Trust Approval
Written final confirmation from the organisation(s) acting as sponsor
REC favourable opinion letter and all correspondence
Confirmation of REC favourable opinion for any substantial amendments

Confirmation of any other regulatory approvals (e.g. NIGB) and all correspondence

N.B. The above checklist provides an overview of the types of documents that will be required for non-CTIMPs. The documents required by R&D will vary depending on whether the research is Sponsored by RDEFT, hosted by RDEFT or portfolio adopted.

For those studies progressing through the CSP RDMIS system, please follow the document submission guidance on IRAS.

For further guidance please contact the R&D Office on the details given in section 5.5 (step 4).

Submission Notes

* Please send the most recent approved version(s). If there have been any changes to these documents after REC approval has been granted; we will require historical versions of these documents and copies of any ethical approvals pertaining to them.

** Please send the most recent approved version(s). If there have been any changes to these documents after REC approval has been granted; we will require historical versions of these documents and copies of any ethical approvals pertaining to them.

*** Please note that copies of GCP certificates may be required for CI's of non-CTIMP studies

**** In the case of commercially-sponsored non-CTIMPs, there are no model agreements. However, the terms of the ABPI model Clinical Trial Agreement (mCTA) should be used as a basis for any contract. For non-commercial sponsored non-CTIMPs, the model Non-Commercial Agreement (mCNA) is preferred.

Contract Administrative Details

Organisation Legal Title	Royal Devon & Exeter NHS Foundation Trust
Organisation Legal Address	Royal Devon & Exeter NHS Foundation Trust RD&E Wonford Barrack Road Exeter EX2 5DW
Authorised Signatory for Commercial Contracts	Medical Director
Authorised Signatory for Non-Commercial Agreements	R&D Directorate Manager
Notices	R&D Directorate Manager R&D Department Floor 3 Noy Scott House RD&E Wonford Barrack Road Exeter, EX2 5DW
Bank Details	This information is available upon request. Please include the following statement where bank details are requested: *"Royal Devon & Exeter NHS Foundation Trust will raise invoices upon notification from you and payment should be made according to invoice instructions."*