NIHR | Clinical Research Network South West Peninsula

Research Support for Investigators in the South West Peninsula

For investigators planning Non-commercial research in the NHS and Social Care

This document is a resource to support investigators in the South West Peninsula who have a health or care related research idea. This document aims to describe the support offered and has been created in collaboration with the SWP CRN and supporting organisations from across the region. Whether you are looking to develop your research idea, apply for funding or understand the research infrastructure within this region, this document can provide you with information and contacts to support you through every step of the research pathway. If you have any further question, please contact the Study Support Service Team.

rch-tr.SWPStudySupportService@nhs.net

Contents

Research and Development (R&D)

As a health and/or social care researcher you should primarily make contact with your institutions Research and Development Department (R&D). Dedicated R&D staff will support you to facilitate high quality research; whilst ensuring that the interests of participants, researchers and the sites are protected through adherence to local and national regulations.

R&D responsibility:

- Sponsorship for some studies (see below).
- To ensure contracts are in place describing the legal responsibilities of researchers.
- Responsible for checking that the research is adequately funded.
- Providing local trust management approval, including the assessment of capability and capacity to deliver the research at their site.
- Providing training in GCP and other research related skills.
- Other activities to maintain the oversight of compliance in research.

Sponsorship

All health and social care research is required to have a sponsor. This includes all research that involves NHS patients, their tissue or data.

It is important that you identify and approach the Sponsor as soon as you have a research concept or idea (the R&D department will support you with this). The Sponsor is the institution that takes on the legal responsibility for the initiation and management of the research study but is not necessarily the funder**. T**hey will guide and support you to ensure that the project incorporates and maintains the appropriate governance standards throughout the project.

Sponsorship responsibility:

- Management of all necessary resources.
- Development of study documentation
- Meeting all legal and ethical requirements.
- Favourable opinion from a Research Ethics Committee and any other relevant approvals.
- Making information about the study publicly available before the research begins.
- Submitting for approval and implementing protocol amendments.
- Reporting progress and findings.
- Dissemination of findings.
- Accessible archiving.
- Ensuring compliance with labelling, reporting and record-keeping requirements and Good Clinical Practice (GCP) https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm
- Ensure proper monitoring of the clinical study

The Sponsor will support your project from concept through to publication and will work with you and the services presented in this guide to ensure that your research is successful.

Developing your Research Idea

Research Design Service:

https://www.nihr.ac.uk/explore-nihr/support/research-design-service.htm

The RDS provides support to health and social care researchers across England on all aspects of developing and writing grant applications including research design, research methods, identifying funding sources and involving patients and the public. Advice is confidential and free of charge.

RDS Project Review Committee (PRC)

Pre Submission projects can be submitted once per month to the SWP project review committee where several RDS reviewers along with lay representatives will review and feedback on the project, more information along with dates for submission can be found here: Research Design Service South West

Clinical trials Units (CTUs):

At the grant application stage it is important that you consider the use of a CTU. Many grants expect the use of a CTU which are specialist units which have been set up to design, conduct, analyse and publish clinical trials and other well-designed studies. There are two CTUs in the South West Peninsula.

They have the capability to provide specialist expert statistical, epidemiological and other methodological advice and coordination to undertake successful clinical trials. In addition, most CTUs will have expertise in the coordination of trials involving investigational medicinal products which must be conducted in compliance with the UK Regulations governing the conduct of clinical trials resulting from the EU Directive for Clinical Trials.

Exeter Clinical Trials Unit | Exeter Clinical Trials Unit (ExeCTU)

Collaborating with ambitious researchers on the design and delivery of high-quality and efficient clinical trials

Exeter CTU work in partnership with researchers and clinicians across the trial lifecycle: refining research questions, optimising study design, developing funding applications, trial set-up and delivery, analysis, write up and dissemination. The team has extensive experience in trials methodology, study design, database programming, trial and data management, monitoring, statistical programming, analysis and reporting. We have experts in health economics, process evaluation and qualitative research and work closely with NIHR

colleagues in the Exeter CRF, the RDS SW and PenARC and other expert methodologists, including in Patient and Public Involvement.

Their trial portfolio includes dementia, mental health, orthopaedics, diabetes, emergency medicine and Covid-19, supported by funding from the NIHR, UKRI, Horizon2020, large charities and others. Studies include regulated drug trials, surgical, device and apps trials and trials of complex interventions, locally in the South West, nationally and internationally.

- **Who's it for**: Researchers looking to answer important healthcare questions by developing high-quality studies and who would like to collaborate with an experienced team to design and deliver the study
- **Geography**: Exeter-based with track record of successful collaborations with local, national and international leading research teams

Peninsula Clinical Trials Unit (PenCTU)

Addressing health and social care challenges through the design, development and delivery of quality-assured research

Maintaining full UKCRC registration status since 2007, PenCTU has collaborated in a large number of clinical trials and other types of study, in a wide range of therapeutic areas, including international regulated drug trials, device trials, trials of complex interventions, cluster randomised trials, pilot/feasibility studies and observational cohort studies, in primary and secondary care settings.

They aim to be the investigator's 'right hand', working with you from design to delivery. Collaborate with our triallists to design your study and develop your funding application. Task our dedicated trial managers with project-management of your study from set-up to completion. Allow our highly skilled developers to create intuitive data capture systems and rely on our data managers to maximise the integrity of your study data. Statisticians involved at the design stage will contribute throughout the project duration and will analyse data, assist with interpretation and help disseminate research findings.

Wherever possible PenCTU aim to tailor our support to your specific requirements in order to deliver efficient and high quality projects.

- **Who's it for?** Experienced investigators and early career researchers alike
- **Geography:** Based on the University of Plymouth's North Campus, co-located with the South West RDS and CRN South West, with whom they work very closely. PenCTU collaborate with investigators based locally, nationally and internationally.

Clinical Research Facility (CRF)

The South West Peninsula has one Clinical Research Facility based at the Royal Devon and Exeter NHS Foundation Trust. Clinical Research Facilities (CRFs) for Experimental Medicine are dedicated facilities where specialist clinical research and support staff from universities and NHS Trusts work together on patient-orientated commercial and non-commercial experimental medicine studies.

For more information about how the CRF can support your research click on this link: Exeter Clinical Research Facility // Home

NIHR ARC South West Peninsula (PenARC)

The NIHR ARC South West Peninsula (PenARC) is one of 15 ARCs across England, part of a £135 million investment by the NIHR to improve the health and care of patients and the public. They are a partnership of NHS Trusts and Local Authorities across Cornwall, Devon and Somerset, plus the Universities of Exeter and Plymouth.

PenARC has three key objectives:

1. To increase the volume and quality of patient-focused research in the SWP
2. To improve health outcomes by more effective use of evidence to drive health services
3. To increase capacity within the health economy to use and generate evidence

PenARC research falls under five main themes, each with its own academic lead

For more information about how PenARC can support you contact: penarc@exeter.ac.uk

University Research and Research Development Manager

Research development managers are employed by the Higher Education Institutes to offer research development and management support and advice to academics across the research project lifecycle from idea to impact. They will support both the research development and financial elements. This includes identifying funding opportunities, co-ordinating bid development and supporting live projects and post project activities.

For research development queries please contact your Research Development Manager (RDM), via the below email addresses:

Exeter University

IBCS & IHR academics: Health-Research@exeter.ac.uk

Psychology or Sport & Exercise Sciences academics: cles-applications@exeter.ac.uk

Plymouth University

doctoralcollege@plymouth.ac.uk

Clinical Research Network Support

Study Support Service (SSS) South West Peninsula

https://sites.google.com/nihr.ac.uk/swsss

The SSS helps investigators/teams with studies eligible for CRN Portfolio adoption. Support is offered regardless of location, study type, study size, therapy or research area. Whether the study is medical, diagnostic, pharmaceutical, bio-tech or looking at healthy populations of people with social care needs, the SSS can support set up and delivery of high quality research to time and target in the NHS and the wider health and social care settings.

Adoption to the portfolio - Benefits

- CRN Support throughout the study lifecycle from idea to archiving
- Signposting and troubleshooting
- Supporting site level costing and attribution of costs for grant applications
- Site identification in England, Scotland, Wales and Ireland.
- Business intelligence and research targeting
- Communications support
- Support and advice about the patient pathway of the target population in the NHS and Social care
- Links to research staff and infrastructure in primary, secondary, tertiary health and social care.
- Dedicated Performance review lead to monitor and support recruitment and performance of research on the portfolio.
- Access to funds which may support identification of participants in the study.

For information about what studies are eligible for CRN support please visit the link below.

https://www.nihr.ac.uk/documents/eligibility-for-nihr-clinical-research-network-support/23746

CRN Research Speciality Lead (RSL)

The CRN RSL can provide support to Investigators who have not worked within these areas about the 'do ability' of a research project in this specialty. They can suggest areas or sites that it might be beneficial to run a research project and can provide specialist knowledge about services in their particular specialty. They can advise about both local sites and can reach out to a network of colleagues across England to provide up to date information about sites across the UK. They can mentor new Chief Investigators or Principle

Investigators within the region or can simply help unblock problems that may be causing delays in getting your research started. The RSL's are very familiar with working in the field of research and if they cannot help with you they may be able to signpost you to someone who can. RSL's are appointed by each Local Clinical Research Network (LCRN) in 30 specialty areas. Specialty areas can be found in **Appendix 2**

CRN Portfolio Review Lead and Performance Review

Performance monitoring is a key part of the NIHR Clinical Research Network Study Support Service. The CRN databases collate site level information to provide study-wide oversight, which enables proactive performance monitoring and helps sites stay on top of study performance to deliver on time and meet recruitment targets.

As part of the SSS, eligible studies will be allocated a Performance Review Lead (Also called Research delivery Manager) who will be responsible for monitoring the progress of the study through its life cycle. The Performance Review Lead will be the main contact point for all study related queries after the study has opened to recruitment.

Feasibility and Site Identification

The CRN Site ID service enables us to liaise with all 15 LCRN's across England to gather expressions of interest and feasibility data from a range of sites across the (UK) to take part in your study. For more information contact rch-tr.SWPStudySupportService@nhs.net

Feasibility in Primary Care

The SWP CRN Clinical Support Team (CST) are able to offer robust feasibility to assess capacity and capability to ensure early study identification of study site and set up and pre-feasibility for Chief Investigators at grant submission and study set up phase. For more information about this contactcrnswp.primarycare@nhs.net or rch-tr.SWPStudySupportService@nhs.net

CRN Business Intelligence Unit (BIU) and research targeting

The CRN Business intelligence service can support optimum targeting of research by analysis and interpretation of Hospital Episode Statistics (HES data) and Quality Outcomes Framework (QoF) Data - disease incidence and prevalence data https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/general-practice-data-hub/quality-outcomes-framework-qof

The BIU can examine the distribution of clinical research activity in comparison to the incidence and prevalence of certain diseases and conditions in England. This can be used to place clinical research in areas of greatest need.

BIU can also provide infographics to support your proposals.

CRN SWP Communications Team

It's important to think about communications before, during and after you run your trial. In doing this you will maximise the chance of raising awareness, finding participants and sites and disseminating your findings to the right audience(s). The CRN Communications team can assist you at every stage.

Study Set –Up

Before you start your trial think about how you will raise awareness and generate interest in it. How will you reach your target audience(s)? Subject to the correct ethics approval, we can:

- Write a website news story about the launch of your trial and encourage participation
- Share content on social media to reach patients, the public and professionals
- Review and give feedback on the your promotional materials
- Advise on promotion through press and media

During the Study

While your study is running we can continue to raise its profile.

- We can use our website and social media channels to advertise for recruitment.
- We're always happy to speak to research participants and delivery staff to create a 'good news' story. You will have sign off of this and the opportunity to position or comment.

Study Closure

People want to hear about your findings and we can help share your results.

- Let us know when you publish results, we can write up a news story about it on our website.
- We can share the results to social media.
- We are happy to support you in gaining local press and media coverage

Ongoing communications support and advice

The CRN communications team is always happy to have a conversation about your communications so please don't hesitate to get in touch if you have any questions or ideas you'd like to discuss.

SWP Digital Research Solutions

South West Peninsula Digital Research Solutions works in collaboration with the CRN SWP and is a group of primary care information system experts, who provide digital IT solution support to enable and help facilitate more efficient delivery of primary care research studies by targeted and intuitive system interrogation tailored to the specific requirements of a research study. This consists of support in the form of standardised clinical system searches to enable the sharing across practices, study pop ups to alert practices to studies and templates for the development of reports and other software options in SystmOne and EMIS. SWP Digital Research Solutions are part of a national network of IT Solutions that support Local Clinical Research Network Delivery in Primary Care by reducing the administrative burden and improve recruitment in research studies. There are real benefits for using this service. The use of shared standardised searches and pop ups encourage wider participation; searches are accurate, efficient, timely and accessible for Chief Investigators, study teams and practices. Engagement and research participation as a whole is increased and set up times improved.

Patient and public involvement and engagement (PPIE)

It is important to consider public involvement for optimum health and social care research

https://www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/involve-patients.htm

The NIHR has published a set of standards to support the PPIE element of your research. https://sites.google.com/nihr.ac.uk/pi-standards/home

At the design stage RDS Research Design Service and/or PenARC Contact Us | PenARC can support the public involvement strategy and activity with advice and potentially some funding.

It's important to give costing and protocol design consideration to the dissemination of results to participants at the end of the study. Recent CRN survey findings showed 86% of patients want to know study results**.**

Early Engagement with investigator teams

It is important that when you have been working with the different groups above that you try to have joint meetings. You can organise this meeting yourself or ask the Study Support Service rch-tr.SWPStudySupportService@nhs.net or your potential sponsor to set it up. Attendees might include but not limited to:

- Chief Investigator

The person designated overall responsibility for the design, conduct and reporting of a study.

- Trial/study manager
- Research Design Service representative
- Co-applicants
- Supervisor
- Potential sponsor e.g. An acute trust or higher education institution - For SWP Sponsors see **Appendix 1**
- Representative from the lead NHS site (if the sponsor is a higher education institution) this might be someone from R&D, nurse, physio etc.
- CRN/Study Support representative rch-tr.SWPStudySupportService@nhs.net
- Clinical Trials Unit representative
- Trust/HEI Finance manager
- Methodologists involved in the bid
- Patient and public involvement and engagement (PPIE) officer.
- PPIE representative
- Research Speciality Lead

Development of a proposal for a funding application

You may need regular meetings during the development of the application for funding; how often and how many of these meetings will depend on the complexity of the study and should be guided by the CI, Sponsor and/or CTU. You may start to circulate the proposal within the group for review and critique.

https://sites.google.com/a/nihr.ac.uk/crn-swp-primary-care-it-working-group/home

Bringing together your wider Costs

Your sponsor representative will be able to provide a contact within the institution to help you bring together your wider costs, please contact the study support service for guidance about the sort of things you need to consider when costing a research grant. rch-tr.SWPStudySupportService@nhs.net

Costs to consider can be found in **Appendix 5**

Calculating your Site Level Costs - the Schedule of Events Costing and Attribution Template (SoECAT)

These are the costs incurred by the NHS, Primary care or DHSC sites to deliver your study. These costs may come from your research grant, the CRN and the CCG. For more information about this go to the government website which describes the attribution of costs of health and social care. (AcoRD)

https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

By stage 2 of the funding application the CI will be asked to complete an excel spreadsheet called a SoECAT (Schedule of events costing and attribution template) with support from the AcoRD expert from the sponsor team. The template and guidance can be found here: https://www.nihr.ac.uk/documents/schedule-of-events-cost-attribution-template-soecat-guidance/23214

If the study is sponsored by an HEI a representative from the lead NHS site should be involved in completion of the document in order to provide accurate information.

When the SoECAT is completed and the sponsor is satisfied that all site level costs have been added, the form will be checked for correct attribution and validated by the lead CRN rch-tr.SWPStudySupportService@nhs.net

A list of SWP sponsors contacts can be found in **Appendix 1**

Submission of Grant application and Sign Off

It's likely that before the application for funding is submitted a sponsor and co-investigator sign off will be required so it's essential that all stakeholders involved in the application are included in correspondence and meetings and then given clear timelines for signatures.

Study Set up

For Clinical trials testing a CTIMP the Clinical trials tool kit should be followed to navigate through the legal and ethical requirements http://www.ct-toolkit.ac.uk/routemap/

Health Research Authority (HRA)

Health Research Authority

HRA is the body that assesses the governance and legal compliance alongside independent ethical opinion by a Research Ethics Committee (REC) for all project based research in England and Wales.

Certain types of research may only need to apply for REC review. For example, studies taking place outside of the NHS where there is a legal or policy requirement for ethical review.

Your sponsor will support your application for approvals.

Medicines and Healthcare Products Regulatory Authority (MHRA)

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

The MHRA is part of the Department of Health. It regulates medicines, medical devices and blood components for transfusion in the UK, and plays a leading role in protecting and improving public health and supporting innovation through scientific research and development.

The MHRA is responsible for:

- ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy
- ensuring that the supply chain for medicines, medical devices and blood components is safe and secure
- promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines
- helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- supporting innovation and research and development that's beneficial to public health

- Influencing UK, EU and international regulatory frameworks so that they're risk-proportionate and effective at protecting public health.

Research Ethics Committee (REC)

REC's decide whether the research is ethical. They are entirely independent of research sponsors, funders and investigators. The REC forms part of the overall HRA review process. For projects that do not require HRA Approval, such as research tissue banks, research databases, or research taking place outside the NHS such as Phase 1 trials in healthy volunteers, REC review may still be required.

Use this tool to check whether your study needs REC Review:

Do I need NHS Ethics approval?

If your study does not require review from a REC it may still need university ethics approval. You should seek advice from your sponsor about this.

Applying for approvals

Whether you are following the HRA Approval or REC-only route, the following steps apply:

- Complete the application form on the Integrated Research Application System (IRAS)

  Integrated Research Application System (IRAS)

- Prepare Study Documents. See **Appendix 3**

- Book your REC appointment on online booking system

- E-submit IRAS form.

CRN Portfolio Adoption

- Eligibility for CRN support:

Eligibility for NIHR Clinical Research Network support

- NIHR Studies e.g. RfpB, HTA, EME, i4i, NIHR Fellowship schemes, NIHR Social Care awards, themed calls. Funding opportunities
- Non-commercial partners https://www.nihr.ac.uk/documents/nihr-non-commercial-partner-list/11458
- Investigator Initiated Trials (IIT)
- Other potentially adoptable awards (if offered in open competition and peer reviewed) for more information contact rch-tr.SWPStudySupportService@nhs.net

Academic Health Science Network (AHSN)

There are 15 Academic Health Science Networks (AHSNs) across England, established by NHS England in 2013 to spread innovation at pace and scale.

As the only bodies that connect NHS and academic organisations, local authorities, the third sector and industry, the AHSN can create the right conditions to facilitate change across whole health and social care economies, with a clear focus on improving outcomes for patients and driving the adoption and spread of innovative ideas and technologies across large populations.

The AHSN can bring people, resources and organisations together quickly, delivering benefits that could not be achieved alone. This Innovation Pathway summarises how AHSNs support the entire innovation life cycle.

The AHSN are particularly interested in seeing healthcare businesses thrive and grow, creating jobs and bringing in investment to the UK.

If you are interested in talking to someone from the AHSN contact: info@swahsn.com

Study Closure

At the end of a study you should declare the end of the study using the appropriate form(s) and provide a final report to the appropriate body (ies) within defined timelines. Your sponsor representative or CRN portfolio review lead will advise you about this.

Declaration of end of study to ethics

The ethics committee which gave a favourable opinion of the research https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/ must be notified of its conclusion, in writing, using the appropriate form found on the HRA or MHRA https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues website.

You should email the appropriate form to the REC within 90 days of the end of the study.

End of study under HRA Approval

If your research has HRA Approval and has been reviewed by a REC you need only inform the REC when your study has ended. Where a project has HRA Approval and was not reviewed by an NHS REC, you will need to tell HRA when the project has ended. You should send this notification by email to approvals@hra.nhs.uk with IRAS ID and your contact information included.

Final reporting

You should send a summary of the final research report to the REC (and MHRA for clinical trials of investigational medicinal products) within 12 months of the end of the study.
There is no standard format for final reports. You will be expected to explain whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research to include any feedback to participants.
You should also consider whether there are any other actions that were determined at the project planning stage, E.g. Is information is to be provided to participants at the end of the study?

Publication of Clinical Trial Results

Sponsors of Clinical Trials of Investigational Medicinal Products (CTIMPs) are required to publish a research summary of their findings on the EudraCT database within one year of the study's completion. This timeline is reduced to six months for paediatric studies. This requirement does not apply to phase 1 research.

Information to participants at the end of a study

It is good practice to disseminate the results of your research to research participants, your PPIE participants and other interested groups or communities. This provides feedback on the outcome of research towards which they have contributed.

Appendix 1

SWP Trust R&D teams websites and contact information

- Cornwall Partnership Trust Research and Innovation
- Devon Partnership Trust Research, development, innovation
- North Devon District Hospital Research and Development Department
- Royal Devon and Exeter NHS Foundation Trust RDE Research
- Royal Cornwall Hospitals NHS Trust Research, Development & Innovation
- Somerset Partnership Trust Somerset NHS Foundation Trust: Home
- South West Ambulance Service NHS Trust Welcome to SWASFT -
- Taunton and Somerset NHS Foundation Trust https://somersetft.nhs.uk/clinical-research/
- Torbay and South Devon Research and Development
- University Hospitals Plymouth NHS Trust ttps://www.plymouthhospitals.nhs.uk/research-contact-us
- Yeovil Hospitals Clinical Research and Development - Yeovil District Hospital NHS Foundation Trust

SWP Higher Education Institutions (HEI's) R&D teams Websites and contact information

- Exeter University Research Development - Exeter Academic
- Plymouth University Researcher development programme

Appendix 2

CRN Research Specialty Areas

1. Ageing
2. Anaesthesia, Perioperative Medicine and Pain Management
3. Cancer
4. Cardiovascular Disease
5. Children and Young People
6. Critical Care
7. Dementia and Neurodegeneration
8. Dermatology
9. Diabetes
10. Ear, Nose and Throat
11. Gastroenterology
12. Genomics and Rare Diseases
13. Haematology
14. Health Services Research
15. Infection
16. Trauma and Emergency Care
17. Kidney Disorders
18. Liver
19. Mental Health
20. Metabolic and Endocrine Disorders
21. Musculoskeletal Disorders
22. Neurological Disorders
23. Ophthalmology
24. Oral and Dental Health
25. Primary Care
26. Public Health and Prevention
27. Reproductive Health
28. Respiratory Disorders
29. Stroke
30. Surgery

Appendix 3

Support Documents required for approvals application

Prepare study documentation

1. Organisation Information Document (OID) for each site type
    - The OID forms the agreement between the participating NHS/HSC organisation and the Sponsor for all non- interventional studies in the UK. (The OID replaced the Statement of Activities and Site Specific Information Forms).
    - The OID should be used to provide information on participating NHS/HSC organisations in the UK. An outline OID for each site type should be completed as part of your submission. OID guidance:

      https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-OID

2. UK Statement of Events / Schedule of Events Cost Attribution Tool (SoECAT) For each site type.

3. The model Non-Commercial Agreement (mNCA) should be used for clinical trials or investigations. https://www.hra.nhs.uk/about-us/news-updates/new-version-uk-wide-model-non-commercial-agreement-mnca-published/

4. Protocol, amendments Participant Information and Consent documents.
    - Your protocol is a full description of your research study and will act as a 'manual' for members of the research team to ensure adherence to the methods outlined
    - Your Participant Information Sheet (PIS) should describe clearly what a potential participant should expect if they agreed to take part in your study

5. Delegation Log
    - This should include team names but signatures should be put in place at set-up
6. Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study eg. Case report forms, lab manuals etc.

7. Relevant supporting documents: These will include some of the documents that have been submitted/approved with the IRAS Form submission and other documents to support study set up at the participating NHS/HSC organisation(s)

Appendix 4

Abbreviations and Acronyms

AAC - Assess, Arrange and Confirm
AHSN- Academic Health Science Network
AMRC -Association of Medical Research Charities
BIU - Business Intelligence Unit
C&C - Capability and Capacity
CCG - Clinical Commissioning Group
CRF - Clinical Research Facility
CRN - Clinical research Network
CTU - Clinical Trials Unit
ETC - Excess treatment Cost
GCP - Good Clinical Practice
HEI - Higher Education Institution
HRA - Health Research Authority
HSC - Health and Social Care
IRAS - Integrated Research Application System
LCRN- Local Clinical research Network
NHS - National Health Centre
NIHR - National Institute of Health Research
OID - Organisation Information Document
PenARC- Peninsula Applied Research Collaboration
PHE - Public Health England
PPIE - Patient and Public Involvement and Engagement
MHRA - Medicines and Healthcare Products Regulatory Authority
PIC- Patient Identification Centre
RC - Research Costs
R&D - Research and Development
RDS - Research Design Services
RDM- Research Delivery Manager
SoECAT - Schedule of Events Costing and Evaluation Tool
Spec Com - Specialist Commissioning
SSC - Service Support Cost

Appendix 5

Top Tips for Costing Research Costs (Version 1. 12/06/2017)

CRN Study Support Service The Research design Service (RDS), Clinical Trials Unit (CTU), Clinical Research Facility (CRF) and/or sponsor will assist you in your grant submission, it is essential that you seek guidance before you submit your bid.

For guidance about the correct attribution of costs, it's important that you consult the NIHR CRN Study Support Service Coordinator for the South West Peninsula Maxine.hough@nhs.net and/or the AcoRD expert who is based in your R&D department.

All your research activities will need to be identified and costed. The 'Statement of Activities' and 'Schedule of Events' templates on the HRA website www.hra.nhs.uk will help you to do this.

Here is a list of costs that will need to be considered:

Salaries

Principle Investigator
University research assistants
Research Nurses
Database manager
Health economist
Statistician
Qualitative researcher
Administrators
Trials unit staff
Physicians

When costing salaries please include:

- Basic hourly salary
- National Insurance and Superannuation
- Incremental rise and date of incremental rise

Remember to include time spent doing:

- All research related activity
- Meetings and training
- Set up time, site initiation etc.
- Close down/archiving time
- Analysis
- Write up
- Dissemination

Equipment

Computers/laptops/printers/basic software
Specialist software
Phones/Smart phones
Wearable Tech
Audio recording/transcription devices
Camera/video recording equipment
Centrifuges
Measuring devices pedometers, actigraphs, scales
Clinical equipment e.g. electronic blood pressure device
Specialist lab equipment
Additional/specialist diagnostic equipment

Travel and Subsistence

Travel and subsistence expenses for participants
Research team travel and subsistence
Travel to and from any meetings for investigators at other sites
PPIE representative expenses
Travel and subsistence for training events.
Travel and subsistence for conferences.

Consumables

Postage e.g. Letter headed paper, postage costs, envelopes, printed labels.
Stationary e.g. Paper, printer ink, folders, pens.
Office equipment
Printing and copying costs

Other Costs

Room Hire
Honorarium for Patient/public representative
Sponsorship Cost
Consultancy fees
Catering for meetings
Transcribing services
Web site set up/design
The cost of promoting the study ie. Posters etc.

**Remember when you are costing for a multi-site study you will need to multiply your costs per site.*