

Get involved in NIHR portfolio research studies as a local Principal Investigator (PI)



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Introduction & Objective Setting

- Develop an awareness of the NIHR and how to get involved in research
- Understand Clinical Research roles
- Understand the role and responsibilities of a local Principal Investigator
- Identify key steps in becoming a local Principal Investigator

Introduction

- Research is a core part of the NHS. Research enables the NHS to improve the current and future health of the people it serves.
- Studies suggest that patients who receive care in research-active institutions have better health outcomes than patients who are treated in a non-research environment.
- The NHS has put in place procedures to ensure patients are notified of opportunities to join in research
- NIHR Clinical Research Network provides an infrastructure to support high quality world-class clinical research within the NHS

NIHR Mission



The NIHR Today

- Since 2009, the total number of patients taking part in clinical trials has tripled, rising from under one million to more than five million.
- 100% of NHS Trusts are now involved in research and are running studies.
- The introduction of [UK Clinical Trials Gateway](#) to make information about ongoing studies available to patients and the public
- CRN BIU Open Data platform – performance charts, recruiting studies by trust, new study opportunities.
- <https://odp.nihr.ac.uk/qlikview/>

NIHR in your area

- The Clinical Research Network is made up of Local Clinical Research Networks (LCRN) that cover the length and breadth of England. These local networks coordinate and support the delivery of research in the NHS and across the wider health and social care environment, in England.
- The Local Clinical Research Networks are overseen by the National Coordinating Centre

Specialities: <https://odp.nihr.ac.uk/qlikview/>

- Over 30 specialities, Tissue Viability research relates to many of them:
- Ageing
- Anaesthesia, perioperative
Medicine and pain management
- Cancer
- Children
- Critical Care
- Dementia and neurodegeneration
- **Dermatology**
- Diabetes

Dermatology Clinical Research Speciality

- Support and promote research in the following areas:
 - Common chronic skin diseases
 - Skin cancers including melanoma, squamous cell carcinoma and basal cell carcinoma
 - Skin infections such as herpes simplex, fungal infections impetigo and cellulitis
 - Children's skin disorders where genetics often plays a major role
 - Rarer skin diseases such as hidradenitis and pyoderma gangrenosum
- Lead on research studies relating to wounds such as venous ulcers and pressure ulcers.

Research Roles

- Chief Investigator (CI)

This is the authorised health professional who takes primary responsibility for the conduct of a study.

- Principal investigator (PI)

- Sponsor

An individual or organisation that takes the responsibility for initiating, managing, monitoring and financing a study, ensuring all arrangements are in place.

- Clinical Research Nurse – Research delivery

- Clinical Trials Assistant – administrative and clinical role

- Advanced Nurse Practitioner (research)

The role of local Principal Investigator (PI)

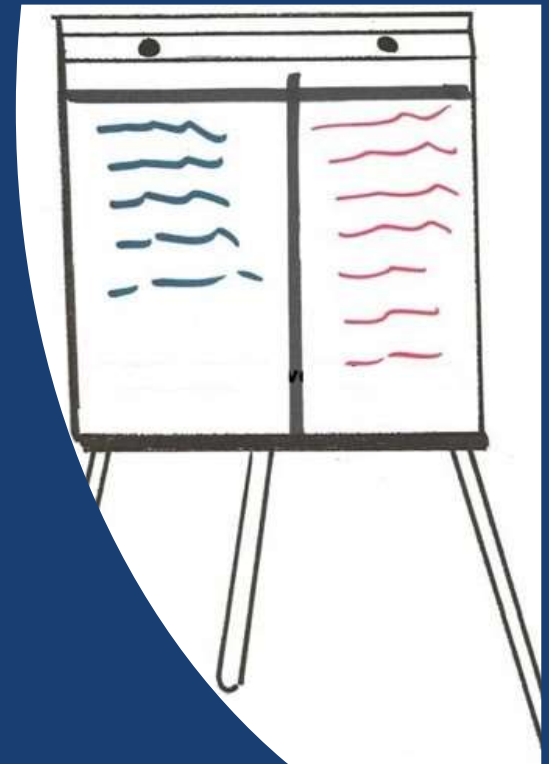
- The PI is the authorised healthcare professional responsible for conducting a trial at their site.
- The PI is usually either a co-applicant involved in the development of a successfully funded multicentre trial or a clinician working within his/her area of interest and expertise.
- Where more than one individual is involved in the research project at one site, the PI is the nominated lead professional for the centre.

Who can be a PI?

What skills and attributes are needed?

In groups:-

- Prioritise your top 3 attributes to share with the group
- Rank the skills by arranging them in order



To add in group feedback

- Medical PI roles
- Nurse PI roles
- Midwives PI role
- AHP PI roles
- Sponsor usually indicates who can take on the role of PI at a site
- Expertise in clinical area, ability to lead a team, knowledge of the protocol, project management skills, awareness of good clinical practice for research, ability to obtain informed consent, understand the roles within the study and ensure appropriate delegation of duties

What barriers
and support is
available?



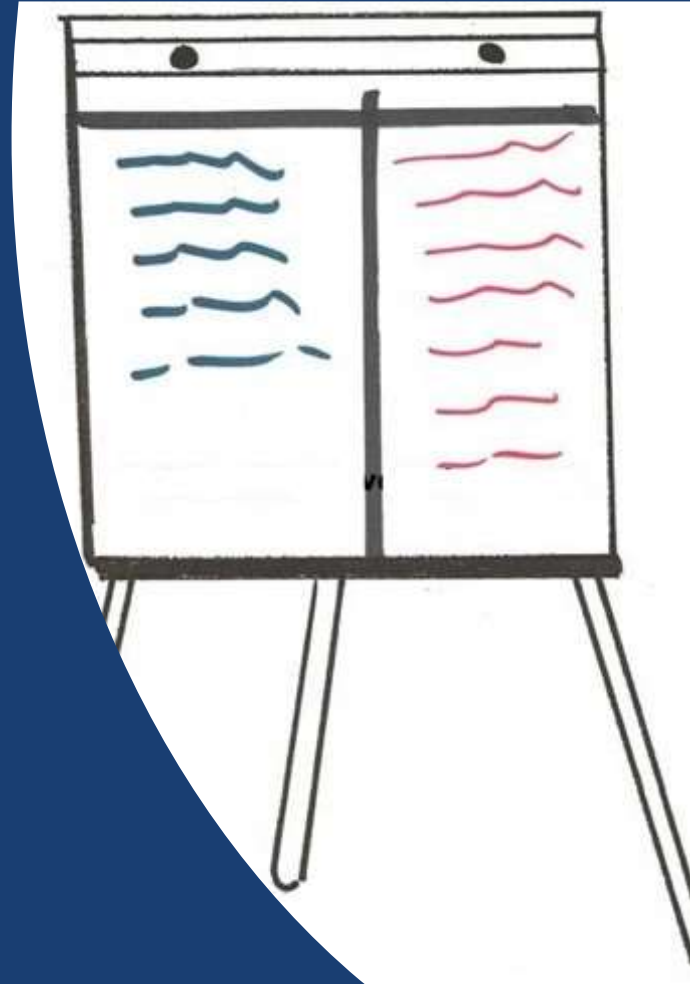
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CQC well led organisations

- Setting up and running a research study in an NHS organisation can involve a number of departments and teams.
- Organisational culture is driven by care targets, research can be seen as 'nice to have' rather than essential so establishing new studies can be difficult.
- The NIHR has no authority over this however the CQC do and having clinical research as an expected activity should help give weight to research priorities

What are the advantages to the role of PI.....

Group Discussion



Advantages to being a PI

- Chance to collaborate with other clinical investigators
- Bring a research culture into the clinic setting
- Offer patients a chance of new therapy
- Be on the leading edge of therapy innovation
- Income generation for the TV Service
- Building Tissue Viability Team

Practicalities/behind-the-scenes PI activity

- Training in the protocol
- Negotiate research team resource
- Understand the clinical pathway
 - Screening
 - Recruitment
 - Intervention
 - Follow-up
- Trial supplies – oversight:
 - Storage
 - Disposal
- Host monitoring visits
- AEs / SAEs/ Interpretation
- Research conduct – oversight:
 - Site file
 - Team standards

Practicalities/behind-the-scenes study tasks – Research Nurses/Team

- Liaising with clinical team
- Screening
- Contacting patients
- Consent
- Visit scheduling (Baseline/Rand/Intervention/Follow-up)
- Randomisation
- Coordinating intervention supplies
- Data recording research forms
- Data monitoring queries

Key steps in becoming a local Principal Investigator

- First speak to R&D and CRN or a colleague within TVS network
- Don't be put off by terminology!
- Learn About Regulations (GCP training)
- Establish the needed infrastructure and support
- Search for Clinical Trials:
<https://odp.nihr.ac.uk/qlikview/>
- Ensure research CV is up to date

Key Steps to becoming a Local PI – Understanding the protocol

- Assess the study protocol and understand the clinical importance of the question
- Have a complete understanding of the nature of the problem/intervention and procedures
- Believe in the null hypothesis or clinical equipoise
- What are the eligibility and exclusion criteria for the study
- Is the study compatible with current clinical practice?
- What is the recruitment rate & can it be met?
- What is the impact on patients (time, investigations, travel, additional appointments)?

key steps in becoming a local Principal Investigator

- Prepare for a Pre-Study Visit (assess feasibility)
- Complete Needed Forms to be an identified site (R&D, IRAS, HRA)
- Obtain local approval - capacity and capability
- Sign the Contract (CTA)
- Get Ready for a Site Initiation Visit (SIV)
- Enrol First Patients (FPFV and RTT)
- Take Advantage of the Opportunity by joining the research community you are actively helping to drive up the standard of healthcare for your patients.



Trial Interventions

Treatment As Usual (TAU)



HydroSurgical Debridement (HD)



DeCellularised Dermis Allograft (DCD)



Negative Pressure Wound Therapy (NPWT)

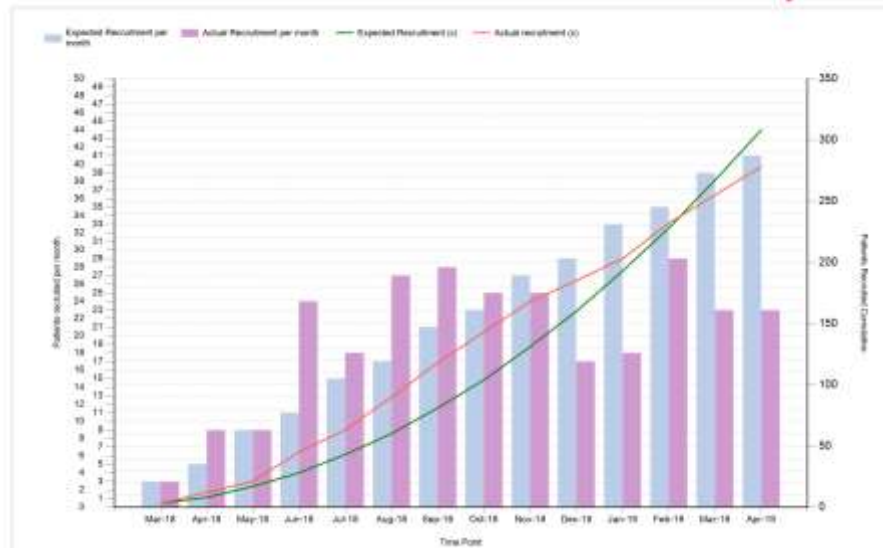




Packing vs non packing of Perianal Abscess Cavities: a multicentre RCT

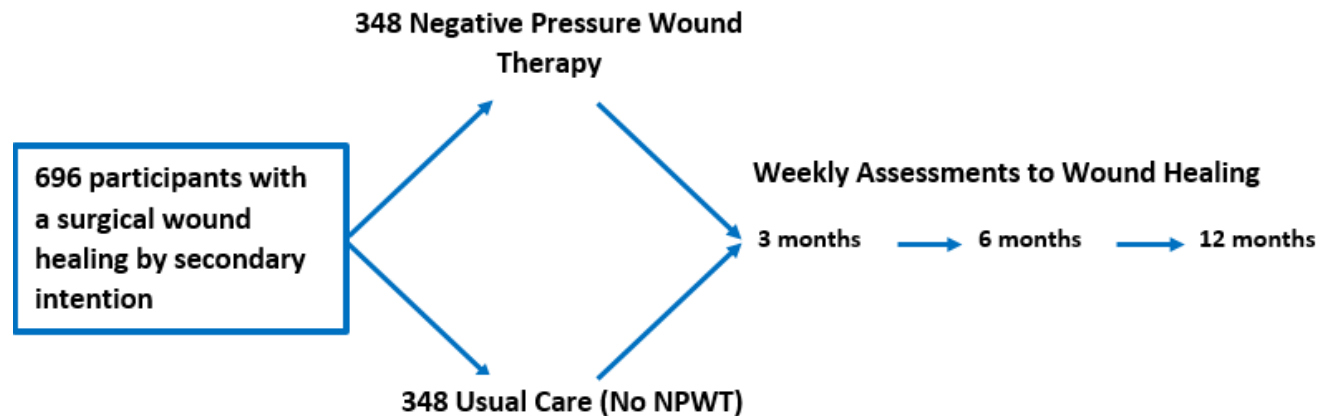
277 patients randomized (target 526)
41 sites open (target 50)

PPAC2 - Recruitment Graph - Actual Vs Expected



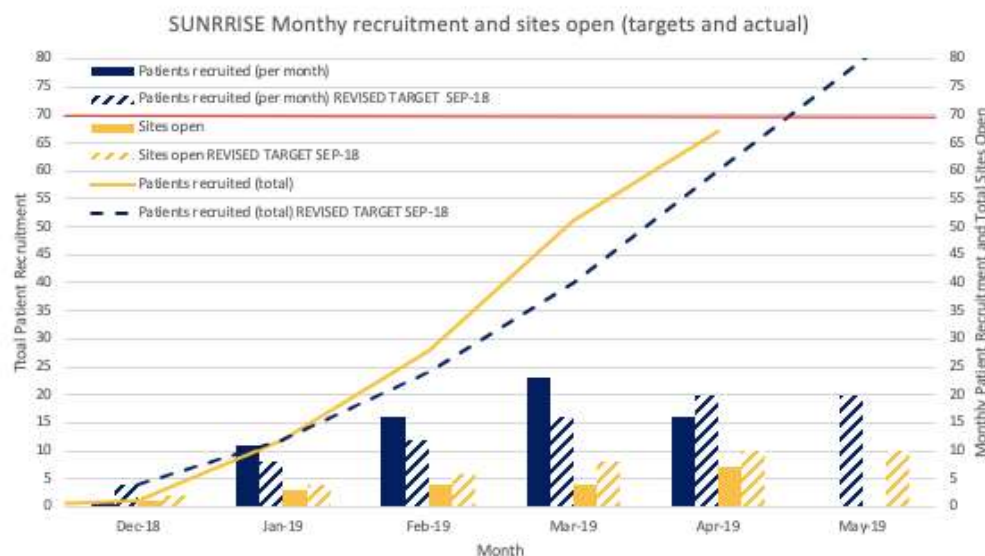


Surgical Wounds Healing by Secondary Intention Trial – 2



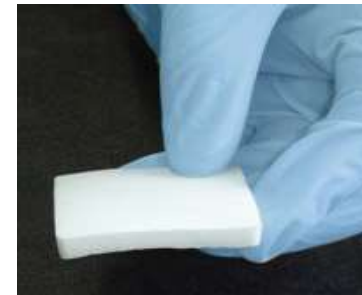


Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy





All abdominal surgery – any incision; any indication; emergency and elective
Including Laparoscopic-assisted with specimen extraction site >5cm



GET INVOLVED

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wounds research network Supported by



Tissue Viability Society

Summary

- The Sponsor, Chief Investigator (CI) and Principal Investigator (PI) are responsible for ensuring the study meets all the required standards.
- Your responsibilities as Principal Investigator (PI) include every aspect of study delivery at your site
- Your role includes leadership of the study and leadership of the site team.
Good communication is essential to success.





Thank you

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