UKCRF NETWORK

Student Placement Toolkit

Guidelines for Use

Version 1 - June 2023

Clinical Research Placement Toolkit

Version 1.0 – June 2023

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Contents

Introduction

This document has been developed to support clinical research areas to supervise students. The guidance from NMC about setting up a placement area, and requirements of practice assessors and supervisors, is for nursing and midwifery student placements but the teaching tools have been designed to be used for any student discipline. The guide has been developed by the UKCRF Network Education & Training Group and is based on best practice from a number of established CRFs.

In addition to information about setting up a placement area, this document contains guidance for supervisors and assessors and suggested learning opportunities for students. An SOP guide has been developed to detail which aspects of care students can participate in, and the level of GCP training required. This may be adapted as required for individual sites.

There is also a pre-placement student orientation pack, intended to be sent out to the student in the weeks before they start so they can think about objectives and a placement workbook with questions to support their personal learning throughout the placement. There are also some placement activity worksheets and answers, that can be taught by any team member to share teaching commitments.

The student packs and activities have been designed so that they can be adapted to meet local needs. It is recognised that different NHS Trusts and Boards will have different requirements for student supervision so the tools can be used as an adjunct to these to enhance student learning opportunities.

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Setting up an Effective Learning Environment

Guidance on how to supervise students on NMC approved programmes can be found in the Standards for Student Supervision and assessment (SSSA).

Introduction to our Standards of Student Supervision and Assessment - The Nursing and Midwifery Council (nmc.org.uk)

It is possible to begin discussions about becoming an approved placement area by contacting the approved Higher Education Institution (HEI) directly or by discussing with your local NHS placement team.

All placement areas must be audited to ensure that they meet required training standards. The audit is usually a collaboration between the HEI, the local NHS placement team and the placement area.

Your local NHS education team can also offer support with training practice supervisors and assessors.

A clinical research area can supervise students without an official audit if the student is coming for a short time as part of a longer placement (i.e., staff would be practice supervisors only). If you are able to offer a few days or a week, it would be possible to discuss options with a linked clinical specialty. E.g., if you specialise in respiratory research, organise with the respiratory ward/clinic practice assessors for students to spend some time with your team.

SOP Guidance

An SOP guidance document is available in appendix 2.

This document details the activities that students could be engaged in, and the level of GCP training recommended. It has been developed to give the research team confidence in what a student can or can't do during the placement. This has been derived from GCP legislation and NMC guidance but can be altered to meet the needs of individual sites. It could be adopted as an SOP or sit alongside a training SOP as a guide.

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Practice Assessor and Supervisor Guide

The role of the research nurse is multi-faceted requiring excellent planning and organisational skills and comprises strong communication not only with patients and families but within the internal and external work teams. It involves working across different specialities as well as within all stages of the research process from feasibility and study set-up to recruitment, to data input, to archiving, providing a multitude of learning opportunities for a student. Students have the opportunity to learn many non-technical skills from a research placement, in addition to practical skills.

Within clinical research we also have a diverse team of health professionals providing specialised care for patients. Students will work alongside a range of staff members to gain a full understanding of all aspects of the research pathway. There may be exposure to new departments including R&D and Local Research Networks and external sponsors. There will be new guidelines to follow (e.g., Good Clinical Practice) and many new terms to understand, however so many new and exciting opportunities to embrace.

The tools provided are designed to be a guide and can either be used in their entirety, or altered to meet the needs of the placement. A pre-placement **orientation pack** is provided (appendix 1) to provide information about the research area, opportunities, and what students should expect. Local information will need to be added to this. This should be emailed out to the student prior to their placement, preferably as a PDF document after relevant insertions have been made. It should encourage the student to think about their objectives and what they might achieve once on placement.

The identification of a practice assessor at an early stage is essential, as this will ensure an initial interview within the first week of placement. This conservation sets the scene and helps the student to confirm not only key objectives but to develop key transferable skills which they can utilise throughout their student journey and beyond. A robust orientation and key learning resources are essential in providing the initial introduction. Following this foundation of knowledge, the student is then able to identify key SMART objectives to enrich their experience.

The following table identifies some learning opportunities for students and suggests extended tasks to enhance learning. These are suggestions only and can be used to help identify learning objectives.

Learning Opportunities

Governance/ Introduction

- Assist your student to create NIHR Learn account and allocate time to complete NIHR Research Practice in Clinical Settings or equivalent training at your site. Consider if full GCP introduction training is required.
- Discuss with your student the various types of approvals required in your research studies, highlighting the relevant documents from your study files and the importance of approval.

Informed Consent

- Discuss with your student the importance of valid informed consent within healthcare and clinical research settings
- Ensure your student observes the informed consent process on both interventional and observational research studies
- Demonstrate to your student the Participant Information Sheet (PIS) and consent documentation held in your study files
- Enable your student to explain a simple observational study to a participant under supervision of the delegated GCP trained research staff

Study Visit

- Arrange for your student to attend a variety of recruitment, baseline and follow up study visits throughout their placement; your student should be able to discuss the purpose of each type of visit but you may have to give more information if needed to fill knowledge gaps

Recruitment

- Explain to your student what is meant by recruitment targets, giving examples from your current studies, and the importance of meeting these targets
- Discuss inclusion and exclusion criteria; ask your student to explain what each term means and their importance in relation to recruitment
- Assess the student's level of understanding about the diseases identified in your participants/studies; ask them to conduct a search on any unknown terms, reporting back their findings to you
- Actively involve your student in study screening and participant identification

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Protocol

- Discuss with your student selected protocols from both interventional and observational studies
- Ask your student to explain the importance of baseline measurements in a research study
- Ask your student to use a protocol and its study procedures table to plan and set up at least one study visit (real or simulation)
- Enable your student to assist in clinical procedures where appropriate and always under supervision of the delegated GCP trained research staff – refer to Clinical Skills
- Supervise to ensure that the student demonstrates compliance with the relevant protocol during all research activity

Clinical skills

- Measuring vital signs, +/- neurological observations
- Measuring height, weight, plus other forms of anthropometry
- Measuring blood glucose
- Undertaking urinalysis, including urine pregnancy testing
- Performing venesection/cannulation
- Performing an ECG
- Taking nasal swabs/brushings
- Participating in clinical procedures and investigations

Medicines management

- Ask your student what is meant by drug accountability in a clinical trial and demonstrate to your student how this is recorded in your studies
- Ask your student to select a selection of medicinal products and to produce a synopsis of each, with reference to their pharmacology and future application.
- Select a patient with a list of concomitant medications and ask the student to find out what they are for and why it's important to record them
- The working group would suggest that students can be involved in administering IMP under direct supervision, but you may have local policy or guidance to determine this.

Documentation

- Discuss with your student research documentation, and the importance of adhering to high standards of information governance
- The working group would suggest that the student can document study visits with a counter signature from a GCP trained member of staff, but you may have a local policy or guidance to determine this.

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Laboratory skills

- Facilitate the student to participate in sample processing as per protocol and under supervision of the delegated GCP trained research staff; arrange a laboratory visit if possible
- Ask the student to describe the importance of accurate sample handling for research participants and study outcomes

Health and Safety

- Run through the Resuscitation Trolley Check, explaining equipment and drugs
- Demonstrate the Drugs Cupboard Checks
- Demonstrate bed space check
- If the student has received up-to-date training in moving and handling, supervise the student in moving and handling activities to gain experience with equipment and techniques
- Ensure your student has received local fire safety induction and facility orientation at the start of their placement
- Invite your student to an emergency scenario training session; explain to your student the historical context of emergency scenario training

Communication/Management

- Task your student with discussing research trial participation with a variety of participants and reporting back to you – questions to consider:
  - *What does 'participating in a clinical trial' mean to them?*
  - *How did they feel when they were approached about taking part?*
  - *Can they identify any advantages/disadvantages of being on a research trial?*
- Facilitate a discussion with your student as to how the research care pathway links in with clinical care
- Organise for student to visit specialist clinics relevant to your research
- Attend meetings within CRF as appropriate

Quality Assurance and Quality Control

- Refer your student to key Standard Operating Procedures (SOPs)
- Demonstrate to your student internal processes in place for quality control including temperature monitoring, document control, QC checking of data, equipment calibration / maintenance; include your student in QC activities where appropriate

Research Roles

- Discuss with your student the various roles and responsibilities of research staff
- Plan for your student to work with a variety of staff in order to gain a broad understanding of working within research – e.g., CTA, CRP, Research Nurse, Research AHP, Trial Administrator, Lab Technician, PI, Research Fellow, Research Trial Pharmacist, QA team, Clinical Research Coordinator etc

A **placement workbook** is also provided to guide learning throughout the placement (appendix 1). Students will need support to complete this in accordance with other placement activities (appendix 2). The workbook contains tasks for the student to complete regarding research processes and encourages reflection about the patient journeys in research. It introduces GCP to the student and suggests further learning. We suggest that GCP awareness training is sufficient and the NHIR online 'Research Practice in Clinical Settings', or local equivalent is suitable for most placements. GCP Introduction training might be appropriate for longer placements, depending on local policies and guidance.

The workbook also suggests a longer project for the student to complete. This will help the practice assessor and supervisor manage time between visits, and encourage the student to do some more in depth learning into an area that interests them. This can be adapted to suit the needs of the placement.

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Placement Activities

This toolkit includes a series of activities that are intended to enhance the learning experience for students on research placements and to help link research practice to theory. They have been designed to support the research team by providing tools to guide discussion topics and learning opportunities. The activities can be delivered by any member of the research team, allowing the practice assessor to share teaching commitments.

The activities can be altered to meet the needs of individual sites and are provided as a teaching tool. They can be used to direct group discussions or be given to students to complete as self-directed learning activities, followed by a feedback discussion. Answers to the activity questions are also provided, and questions to guide discussions are suggested where applicable.

Links to all these documents are listed in appendix 1.

The activities cover the following topics:

- **Introduction to Clinical Research**
- **Informed Consent**
- **Placebo Control and Blinding**
- **Safety Reporting**
- **Protocol Review**
- **Standard operating Procedures**
- **Medicines Management**
- **Emergency Response**

An example of how the learning opportunities, workbook and activities could be linked is suggested below:

	Week1	Week2	Week3	Week4	Week 5	Week 6
Workbook tasks to be completed during week	A,B,C GCP awareness	D,E,I,J	F,G, K Introduce presentation	L, H Work on presentation	M Work on presentation	 Complete presentation
Practical learning opportunities	Variety of **study visits** to maximise **clinical skill** opportunities, **Governance/ Induction** and **Health and safety** learning opportunities	**Informed consent** visits, Review PIS and discuss with participant, **QA** learning opportunities	**Protocol** learning opportunities **Recruitment** and disease knowledge from inclusion and exclusion criteria, **Lab skills**	**Protocol** learning opportunities including using a protocol to plan a visit, **Medicine management** learning opportunities such as drug accountability and knowledge of con meds	Consolidate knowledge including **Documentation** learning opportunities Experience different **research roles** by working with a variety of team members	**Communication and management** learning opportunities

Activity and discussion at end of week to consolidate learning	Introduction to Clinical Research	Informed consent Standard Operating Procedures	Protocol Review Placebo Control and Blinding	Medicines Management Safety Reporting	Emergency Response	Student to present

Appendix 1: List of Toolkit Resources

All documents can be downloaded for free by clicking here (google drive folder).

All documents can be edited and adapted locally, but please ensure that the UKCRF Network is acknowledged.

All documents are also available for free download from the UKCRF Network Portal. If you do not already have access to the Network's portal, you will need to complete a request form on the UKCRF Network website by clicking here.

UKCRFN Student Placement Toolkit includes:

- UKCRFN Student Placement Toolkit – Guides for Use (this document)
- UKCRFN Guideline for supervision and oversight of students on research placements (see Appendix 2)
- UKCRFN Student Placement Activities & Answers (see Appendix 3)
- UKCRFN Student Orientation Pack
- UKCRFN Student Workbook

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Appendix 2: Guideline for supervision and oversight of students on research placements

This guidance document is intended to support students in clinical research placements, describing the requirements for their training and supervision. It is designed to be used alongside or as part of a local training SOP and can be altered to suit the needs of individual sites.

Guideline for supervision and oversight of students on research placements

Background

Clinical research placements are an opportunity to demonstrate research in practice and promote research careers, but students are required to work within the requirements of Good Clinical Practice. This document will outline the training and supervision requirements.

NMC Code

The NMC Code (2018) gives clear instructions that a nurse or midwife must:

- *Share their skills, knowledge, and experience for the benefit of people receiving care and your colleagues. To achieve this, you must:*
    - *Support students' and colleagues' learning to help them develop their professional competence and confidence.*

In addition to this, the NMC Future Nurse: Standards of proficiency for registered nurses (2018) states that a registered nurse will:

- *Support and supervise students in the delivery of nursing care, promoting reflection and providing constructive feedback, and evaluating and documenting their performance'.*

All nurses and midwives have a responsibility to support and train students. Nurses and Midwives must be able to demonstrate an understanding of research methods, ethics, and governance, and completing a research placement is an ideal opportunity for a student to develop this knowledge.

Regulatory Requirements

SI 2004/1031 requires that

- '*Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks'*, and the MHRA GCP Guide (2012) states '*that the PI may delegate activities to appropriate members of the research team but must ensure that the member of staff holds appropriate qualification for the role'*.

The MHRA GCP Guide (2012) further describes the regulators expectations for delegation of tasks in clinical trials:

- '*The need for further trial-specific training can be assessed by taking into consideration the tasks performed by the staff and assessing whether these tasks are the same as those performed for standard clinical care. If this is the case, trial-specific training and delegation of responsibilities may not always be required.*

In addition to this, students will always be supervised by a GCP trained member of staff and will only participate in supervised research activities.

GCP training

Students are required to undertake GCP training tailored to their roles and responsibilities. This will usually be dictated by the length of the placement and may include GCP awareness training for those on shorter placements, or full GCP for those on longer placements.

Supervision and oversight of students on research placements

1. Students will be supervised by a qualified member of research staff who has completed GCP training.
2. The students are not required to sign a delegation log. The supervising staff member delegated to the research study will countersign any documentation to demonstrate oversight and responsibility.
3. Students will undertake clinical procedures and activities suitable to their level of training and experience.
4. Students will undertake research specific activities as a training event, and will be fully supervised throughout (e.g., IMP administration and Laboratory work)
5. The supervising research staff member remains responsible for ensuring that the research is conducted to GCP and the protocol requirements.

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Appendix 3: UKCRFN Student Placement Activities & Answers

All the below documents can be downloaded using this link (google drive folder).

1. Introduction to Clinical Research

This activity provides a brief history of clinical trials and a series of questions. This can be given to a student in their first week to enhance their understanding of the need for regulation. It is recommended that a discussion is had with the student after they have completed it to ensure they have understood the concepts.

Resources:

- Introduction to Clinical Research - Worksheet
- Introduction to Clinical Research – Supervisor Guide and Answers

2. Protocol Review

This session can use any protocol from the researcher's portfolio. It uses a series of questions to highlight how to use the protocol to conduct a study visit. It also visits many research terms and links them to the theory that the student will have learnt in university. There is an opportunity here also for the student to learn more about clinical disease by finding out what the inclusion and exclusion criteria mean and discuss findings with the researcher. This session would be useful to complete with the student before giving them the workbook task of planning a patient visit.

Resources:

- Protocol Review - Worksheet
- Protocol Review – Supervisor Guide and Answers

3. Informed Consent

This session requires some initial work from the student to define and understand informed consent and link it to clinical examples from previous placements. It then uses a media clip saved on YouTube of a poor consent discussion, to highlight bad practice. The researcher should discuss the media clip outcomes with the student. This session could be completed after the student has completed the informed consent section in the workbook and observed informed consent in practice.

Resources:

- Informed Consent – video demonstration (opens in YouTube)
- Informed Consent –Worksheet
- Informed Consent – Supervisor Guide and Answers

4. Standard Operating Procedures

This activity highlights the importance of repeatability and uniformity in research, linking theory to practice. It requires the student to write down the steps of a simple clinical SOP and compare with a corresponding site SOP.

Resources:

- Standard Operating Procedures – Worksheet
- Standard Operating Procedures – Supervisor Guide and Answers

5. Placebo Control and Blinding

The student has some questions to complete, identifying the importance of placebo and then asks them to consider the practicalities of blinding patients and staff in a clinical trial. These outcomes should be discussed with the student.

Resources:

- Placebo Control and Blinding – Worksheet
- Placebo Control and Blinding – Supervisor Guide and Answers

6. Medicines Management

This session asks the student to consider compliance with medication in clinical trials and highlights medicines management policies. There is a practical scenario, allowing the students to practise drawing up IV medications in a controlled environment.

Resources:

- Medicines Management – Worksheet
- Medicines Management - Supervisor Guide and Answers

7. Safety Reporting

This activity requires the student to consider the safety of patients in clinical trials and consists of a series of definition questions followed by some scenarios. The answers and importance of reporting can be discussed with the student.

Resources:

- Safety reporting – Worksheet
- Safety reporting – Supervisor Guide and Answers

8. Emergency Response

Students are asked to watch the documentary about Northwick Park and consider what could have been done differently to ensure the safety of the participants. This session can lead into a discussion about emergency response in research and the importance of simulated practice to maintain clinical skills. A scenario could be run to allow the student to participate in a resuscitation attempt. This session is complemented by the anaphylaxis question in the workbook.

Resources:

- Emergency Response - Worksheet
- Emergency Response - Supervisor Guide and Answers

Appendix 4: UKCRFN Research Placement Toolkit Delivery Team

The members of UKCRFN Education and Training Workgroup are responsible for reviewing and maintaining all documents included in the Research Placement Toolkit for Students.

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