NOC CRF
USER GUIDE FOR RESEARCH TEAMS

MAIN CONTACT DETAILS

Name	Details		Work phone
NOC Helpdesk (G4S)	HELP DESK NOC		38010
SECURITY:	OUH SECURITY		38012
CLEANING:			VIA G4S HELPDESK
CRF Phone numbers	MAIN BAY FEMALE		37998
	MAIN BAY MALE:		37997
	CONSULTING ROOM:		37292
	CONSULTING ROOM/WAIT AREA		37359
	ULTRASOUND ROOM:		37285
Pharmacy Contacts	PHARMACY CLINICAL TRIALS PHARMACY CHURCHILL		72151
	PHARMACY DISTRIBUTION		25977
RED EMERGENCY ANALOGUE PHONE NUMBER			01865 (4)62369
Cushla Cooper	Clinical Operational Lead	cushla.cooper@ndorms.ox.ac.uk	01865 737846
Tha Htet	CRF Administrator	Tha.htet@ndorms.ox.ac.uk	01865 857812

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1. INTRODUCTION

NIHR Oxford Clinical Research Facilities provides a resource for experimental medicine research across both the University of Oxford and the Oxford University Hospitals NHS Foundation Trust. The facilities emerged from the success and impact of translational research at Oxford NIHR Biomedical Research Centre (BRC).

The NIHR Oxford Clinical Research Facility (CRF) consists of a number of spaces across the OUH campus. It includes the EMCRF located on the Churchill Site, and the Nuffield Orthopaedic Centre (NOC) CRF.

This document clarifies daily operational practices within the NOC CRF of which all users must familiarise themselves.

Further details regarding the facility's governance management are found in NIHR Oxford CRF's Operational Policy https://www.ndorms.ox.ac.uk/oxford-emcrf/oxford-emcrf

2. SCOPE OF PRACTICE FOR NOC CRF

The NOC CRF is space embedded into the OUH Foundation Trust and therefore the physical buildings and facilities are managed by the OUH Estates Team.

The clinical and research governance is managed by the NIHR Oxford CRF. Trust SOPs, and standards of practice are applicable to all practices within the CRF and must be adhered to.

3. GENERAL

3.1. EMERGENCY CONTACTS

Clinical Emergency involving participants: 2222
All other Emergencies: 4444

3.2. NON-EMERGENCY CONTACTS (related to the building eg: leaking toilet)

G4S Helpdesk at the NOC in the first instance (ext 38010) and then please report any issue to the NIHR Oxford CRF Operational Team: oxcrf@ndorms.ox.ac.uk

3.3. FIRE

The Fire Assembly point is outside the Haemophilia Centre, across the road by the small car park.
Please refer to the Red Folder in the Nurses Station in the NOC CRF for Evacuation information and guidance for Fire Incident Co-ordinator.
Each study team using the space should nominate a fire co-ordinator and a list of names will be recorded in the Red Folder.

3.4. FIRST AID

First Aid box including Eye Wash on the wall on the main corridor.

3.5. OPENING HOURS And LOCATION

The NOC CRF is a day unit only. There are no capabilities for overnight stays.

The NOC CRF is situated via the covered walkway, to the left of the Haemophilia and Thrombosis Centre and is opposite the Breast Screening facility. It can be accessed from the Breast Screening corridor, immediately adjacent to Breast Screening Reception. NOC CRF can also be accessed via the main hospital, 1st floor, by following the corridor along past wards D, E and F, past the Lecture Theatre and down the steps to the NOC CRF on the left.

4. RESPONSIBILITIES

4.1. Principal Investigator

The PI has responsibility for all study conduct in the facility. Adequate staffing and medical cover must be available for all study visits. PIs will be asked to sign a PI Responsibility declaration.
NIHR Oxford CRF have the right to cease study activity in the facility.

4.2. Study Teams

Study teams are responsible for their participants during study visits. Study teams need to be aware of the daily tasks required during participant visits and complete the required forms/checks related to these (see Appendix 1).

Daily checks should be completed ahead of any participant activity.
Study Teams may also be required to complete the required clinical audits on MyAssure. Team leads should provide nominated names to the CRF Operational Lead so access can be given to the audits.

4.3. Honorary Contracts

If study team members are employed by the University, they must hold Honorary OUH Trust Contracts or valid Research Passports to undertake clinical research activity in the NIHR Oxford CRFs.

5. INDUCTION AND TRAINING

Study teams utilising the NOC CRF will need to adhere to their OUH contract obligations and maintain required training. For any procedures performed at the NOC CRF, the clinical practitioner performing the procedure (ie: synovial biopsy) must provide evidence of their qualification to undertake the procedure.

Study teams will hold their own training records that need to be made available to the CRF team if required (for example; for audit purposes). The training records must include an acknowledgement of this document.

5.1. ACCESS

Fob access is authorised by the Operational Lead (or delegate). Access to the NOC CRF will only be granted as and when required. Access to the building and security is maintained by the OUH Estates team (G4S) via main hospital reception at the NOC.

If any study team members are accessing the facility outside of their protocol remit, they may have their access revoked at the discretion of the CRF Management Group.

Once all study visits in the facility are complete, access will be removed. Reinstating access will be coordinated through discussions between the study team and the Operational Lead (or delegate).

6. GENERAL HOUSEKEEPING

Please ensure the following guidelines are considered during use of the facility:

- Stock levels – if quantities of basic consumables are low, please notify the Core CRF team via oxcrf@ndorms.ox.ac.uk
- At the start of participant visits, the study team are responsible for checking they have the required equipment and consumables to hand.
- Phones in the facility are for business use only and must not be used to make personal calls. Use of mobile phones for personal calls or for work not related to the current study must be made outside of the clinical areas and not at the detriment of participant care.
- Lone Working with study participants is **NOT allowed** in the NOC CRF space in any circumstances.
- Study documentation, including ISFs, should not be left in the NOC CRF once the team leave the area.

- INCIDENT REPORTING - Ulysses should be utilised to report any incidents that occur in the NOC CRF. A copy of the report or the incident number must be reported to the CRF Management team via oxcrf@ndorms.ox.ac.uk
- CLEANING - Staff utilising the facility are expected to clean after their participant visits appropriately and tidy up at the end of their session in the NOC CRF. The unit is cleaned by OUH Trust cleaning services.
- Team members registered with MyAssure should check if any clinical audits due and work to complete these where possible.

7. STAFFING

Study teams utilising the NOC CRF space will be self-sufficient; in that they have the nursing/administrative/practitioner support that they require within their own study team.

However, if any additional or ad-hoc support is required from the core CRF team, please liaise with the Senior RN or Operational Lead based over in the EMCRF, on the Churchill site to discuss options.

8. Medical Cover

PIs must arrange medical cover for all their study activity within the NOC CRF. The name of the covering clinician and their contact details (mobile telephone, bleep, etc) will be collected as part of the Green Light review.

9. CONSUMABLES

Standard ward consumables are provided for use in the NOC CRF (eg: items required for venepuncture). The CRF will not provide consumable items that are not used across studies. It is the study teams' responsibility to ensure any out-of-date consumables are discarded appropriately and all remaining consumables removed at the last study participant visit.

There *may be* space in the Equipment Store for Research teams to store study specific consumables. The teams are responsible for ensuring that these are stored appropriately, clearly labelled with the study ID and contact details.

Teams must discuss any consumable storage with the Clinical Operational Lead/EMCRF Senior Research Nurse during site set-up.

10. EQUIPMENT

It is the user's responsibility to ensure they are appropriately trained and competent in the use of the clinical equipment in the facility.

10.1. Study Specific Equipment

Specialist equipment brought into the facility for specific studies must undergo a Risk Assessment by the study team and shared with the CRF management team; and details of the equipment provided for logging into the CRF Equipment Registry.

Equipment brought into the facility must be clearly labelled, showing the department of origin, the study title and contact details. The responsibility of such equipment remains with the study team and PI, this includes responsibility for its safety i.e.: electrical testing, service, and maintenance. This equipment is for the use of the assigned study team only and should not be used by other teams.

Once the use of the equipment within the study is complete, it must be removed. Please request a copy of the Equipment SOP if further details are required.

11. IT

- All telephones are OUH digital telephone. There is a red telephone by the breast screening reception area which can be used for resus calls if the digital phones are not working.
- OUH WiFi and Eduroam are available in the building.
- Zebra label printer, located in the main nurses' station - PNAWBCTUREC-1.
- OUH IT services will oversee any IT issues related to OUH devices and network – please report these as per standard practice via Service NOW and if not resolved by the time you leave the NOC CRF, please inform the CRF management team.
- There are OUH PC's and COWs available in the facility for use by the research teams.

12. MEDICINES MANAGEMENT

All teams using the NOC CRF must follow the OUH Trust Medicines Policy and associated policies for the safe storage and administration of medicines in the facility. The policy includes Investigational Medicinal Products (IMPs), approved medicines for ward stock and emergency medicines.

13. CLINICAL AREAS

13.1. Flexible Bed Space (2 x 2-bedded bays)

The NOC CRF has two co-joined, 2-bedded bays. Each one has ensuite toilet facilities, patient monitoring equipment and is overseen by the nursing station. The bays are a mixture of recliner chairs, bedside chairs and hospital plinths/trollies. They can be set up and furnished to suit your study requirements.

13.2. Consulting Rooms

There are two Consulting Rooms for use, accessed from the Breast Screening corridor.

13.3. Treatment Room/Ultrasound Room

The Treatment/Ultrasound room is designed to accommodate small clean procedures, such as lumbar punctures, skin biopsies, ultrasound, etc. Users of the Treatment Room must OUH practice guidelines. The study team are responsible for ensuring they have the necessary equipment for each procedure.

To ensure optimal utilisation of the room and equipment, please inform the research radiographer (RR) in advance of any planned use and any specific imaging support requirements. The RR is responsible for the imaging equipment within the NOC CRF.

13.3.1. Clinical Procedural Policies

The process for clinical procedures undertaken in the facility will largely follow the LOCSSIP and NATSSIPs available on the OUH Intranet.

If study protocols indicate following these is not possible, study teams must develop their own written process and submit this for review to NIHR Oxford CRF, prior to the procedure taking place.

13.4. DEXA Scanner Room

The DEXA room is only to be used for the purposes of DEXA scanning and should not be used for any other purpose. To access the DEXA scanner for research purposes, please contact the research radiographer (talita.mzendah@ndorms.ox.ac.uk)

Local radiation protection rules apply to the DEXA room. Consequently, unauthorised personnel are strictly prohibited from entering the room without prior authorisation or supervision from the RR.

14. LABORATORY

The NOC CRF has one small laboratory processing area which contains two centrifuge machines, one of which is refrigerated. The storage is for temporary storage only. These provide equipment and facilities to undertake prompt and careful processing of samples taken on the CRF. Samples will either be shipped for immediate analysis or moved to study specific cold storage external to the NOC CRF.

See Laboratory Code of Practice for further information. (LE-SOP-002)

14.1. Cold storage temperature monitoring

All cold storage units in the NOC CRF must have their temperature monitored. This is done manually as part of the daily checks.

Laboratory Cold Storage	**Temperature range (°C)**
-20°C Freezer, Laboratory	-25.5 to -15.0
+4 Sample Fridge, Laboratory	0.0 to 8.0
Ultra Freezers, DEXA room	-90.0 to -60.0
Pharmacy +4 Fridge	0.0 to 8.0

Temperature deviations should be recorded on the daily checklist and reported to the CRF Management team via oxcrf@ndorms.ox.ac.uk.

Study teams will be notified of any temperature excursions which occur where their samples, or lab kits are stored, so appropriate action can be taken.

Any spillage must be cleaned according to OUH policy.

15. PATIENT VISIT MANAGEMENT

15.1. Recording Participant Encounters (Electronic Patient Records – EPR)

Participants who are receiving a treatment or undergoing an intervention must be admitted into and discharged from the unit on EPR. The study team is responsible for doing this.

To note – healthy volunteers who participate in research are registered as research participants on EPR with a code distinct to the research activities in the CRF. This facilitates use of Trust services particularly the analysis of samples in Trust laboratories, imaging requests and reports and medicines management. Although this creates a healthcare record for each volunteer, medical history will be absent or scant. Recording the GP contact details ensures the researchers can contact the GP as required for the study.

15.2. Food & Drink

There is no formal provision for food and drink preparation. There is a piped water cooler in Consulting Room 1. Anything else will have to be organised by the study team. Standard lite bites/snack boxes can be ordered via the Help Desk ext 38010.

16. Daily Safety Huddle

If there is more than one study team utilising the CRF at the same time, a Huddle is required. The huddle can be led by any of the study nursing team present. This will be used to:

- Introduce study teams present
- Review what is happening in the facility on the day;
- Indicate any equipment issues; or
- Particular participant procedures that may impact on rooms/equipment etc; and
- Divide daily checks
- Any other relevant information

Study team members in attendance are expected to feed information back to their teams as appropriate.

17. Feedback

Oxford EMCRF would welcome feedback from both participants and research groups who use the facility. Research groups are asked to contact the Oxford EMCRF team with comments and suggestions.

Doc/V. No.	Effective Date	Significant Changes	Reason for Change	Previous V. No.
-	-	Not applicable, this is the 1st version		NA

APPENDIX 1

NOC CRF DAILY CHECKS

- NURSE CALL SYSTEM

  Check the call bells are working in the clinical areas.

- SECURITY

  All windows should be locked when not in use. All windows must be closed and locked before staff leave.

- TEMPERATURE MONITORING

  These needs checking manually, until a digital telemetry system has been implemented. Logs are available via the QR code Checklist.

- EQUIPMENT CHECKS

  Visually inspect the equipment in use; and **test PoC equipment**. Any issues must be recorded on the checklist and reported to oxcrf@ndorms.ox.ac.uk

  Equipment to be checked:

  - Glucometer
  - ECG
  - Blood Pressure monitor

- RESUS TROLLEY

  Checked as per MyKitCheck requirements ie: daily/monthly/replenish

- GENERAL HOUSEKEEPING

  This involves a general check of the space to ensure it is clean and tidy. If it appears obvious that cleaning hasn't occurred; linen not taken or waste cleared, please report this to the helpdesk and arrange a time for this to occur.

- MYASSURE AUDITS

  Nominated study team members are responsible for completing required clinical audits via MyAssure Hub for the CRF space.