



**National Institute for  
Health Research**

# **CLINICAL RESEARCH FACILITY (CRF)**

Induction booklet

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# Welcome!

## Welcome to the National Institute of Health Research Oxford cognitive health Clinical Research Facility, Warneford Hospital

The aim of this document is to provide information about the Clinical Research Facility, introduce you to the team, and act as a guide to the tasks you will be required to complete throughout your induction.

*(To be used in addition to the mandatory Trust induction and the CRF Induction Checklist).*

### Background

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#### National Institute for Health Research (NIHR)

The NIHR aims to improve the health and wealth of the nation through research evidence.

The NIHR Clinical Research Network comprises of:

- Six “Topic” Research Networks (covering Cancer, Dementia and Neurodegenerative Diseases, Diabetes, Medicines for Children, Mental Health and Stroke)

- A Primary Care Research Network to support research in this part of the health service
- A Comprehensive Clinical Research Network, which covers all other disease areas.

The NIHR Clinical Research Network Coordinating Centre is responsible for managing the overall performance of the Networks. In addition to this, the Coordinating Centre team develops and delivers streamlined central systems, and undertakes specialist cross-cutting activities to support the commercial life-sciences industry, develop the research workforce, and promote patient and public involvement in clinical trials.

In September 2012, the NIHR made an investment of £102 million, to allow for further development of 19 CRFs across the country. One of these was the Oxford cognitive health Clinical Research Facility, on the Warneford Site; an eight bed CRF dedicated to conducting high-quality mental health research. This funding enables the facility to host an environment conducive to high quality research, covering the running costs of the facility, the equipment and the availability of research staff.

#### Collaborative working with the University of Oxford

The Oxford cognitive health Clinical Research Facility at the Warneford site works collaboratively with the Oxford University, Department of Psychiatry to produce high quality clinical research.

#### Working with industry

A central aim of the research networks is to strengthen research collaboration with industry and ensure that the NHS provides a competitive environment for conducting clinical research. When industry studies are conducted by the team, this is undertaken on a transparent, full cost recovery basis.

#### Working with students

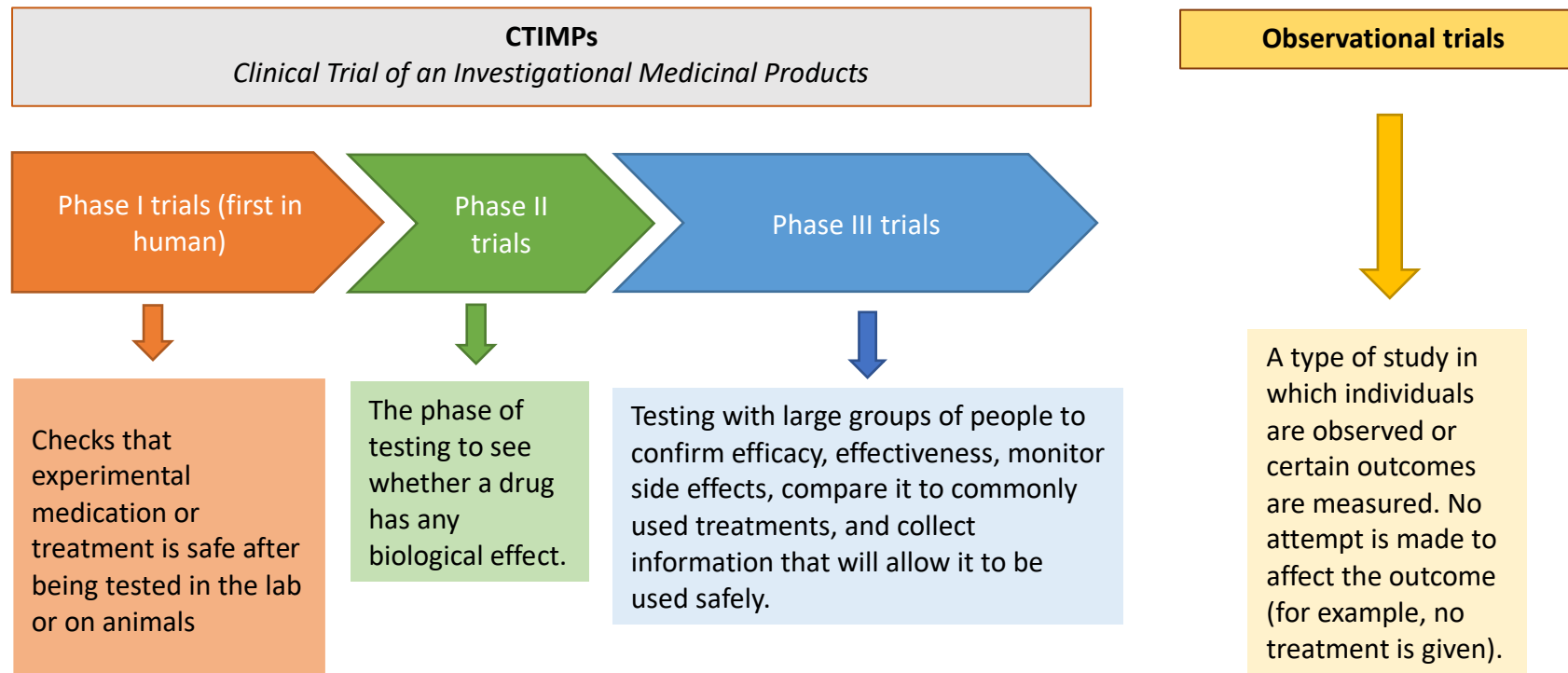
The Oxford cognitive health Clinical Research Facility is delighted to welcome medical and nursing students for full study placements, or to come and spend a day or two with us shadowing our work and discussing our role. This gives students a unique opportunity to gain an insight into clinical research and learn about how evidence-based knowledge is generated. We hope that, by spending time with research staff, students will go on to promote clinical research in their practice and even become actively involved in projects once qualified.

## Clinical Research Facilities (CRFs)



Clinical Research Facilities (CRFs) are purpose-built units, whose facilities are dedicated to experimental medical research and carrying out clinical trials. As part of the National Institute for Health Research (NIHR), CRFs help to provide the infrastructure that allows high-quality clinical research to take place in the NHS, so that we can learn how to improve NHS healthcare for the future. Vitrally, CRFs allow for an active transition to be made between scientific advancements in treatment, diagnostics and care and direct benefits for patients.

Within the research cycle, Oxford cognitive health Clinical Research Facility is involved in carrying out experimental medicine trials, Clinical Trials of Investigational Medicinal Products (CTIMPs), especially Phase 2 upwards and Observational Trials.



## Induction at the CRF

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A survey was developed in 2017 to explore the usefulness of the research initiatives in place at the time for new starters, and their perceived efficacy for the development of confident and competent research practitioners. The survey study recruited all clinical band 5 and 6 nursing staff working on the CRF and collected data that evaluated the induction initiatives available for research staff. These included both mandatory and in-house activities. The survey collected data relating to staff confidence, development and perceptions of support with regard to these initiatives.

Findings emphasised the positive role of teamwork and the challenging experiences of staff relating to knowledge and structure in the delivery of the induction pathway at the time. Results showed that although staff felt supported by the team, there was a pressing need for a structured induction package to facilitate the transition to clinical research at the CRF. A poster was developed for the 13th UKCRFNetwork Conference with the results of this work.

The present induction package was developed based on this study and since updated to reflect any recent changes in the induction process. This package includes an in-house component which aims to provide consistent support for staff, a training component that is informed by up-to-date policies and standard operating procedures, trial-specific training, and designated mentorship for every new starter.

The CRF understands that a smooth transition between conventional clinical practice and the research environment is crucial to ensure efficient and effective team working, to promote professional development, to retain site competitiveness and to accommodate new research projects in a timely manner. An improved and refined research induction programme that delivers mandatory and in-house initiatives in a structured format has been created to support nurses in the beginning of their clinical research careers and promote the development of confident practitioners.

CRF-specific documents are currently stored in our G-drive: Oxfordshire>Clinical Research Unit.

To view the Trust Induction Information for Staff and the OHFT Induction Policy, go onto the OHFT Intranet and click on the Policies and Procedures tab. Select '3 Human Resources Policies', then 'Induction Policy' and in this folder you will find both documents which will be useful to read.

Normal working hours for CRF staff are between 9am and 5pm, however working from 8am-4pm is available for all staff on one designated day of the week on a trial basis. This is to be discussed with management during the induction period.

We hope that this improved structured programme meets your needs and support you in the beginning of your clinical research career. We appreciate any suggestions and ideas you may have to contribute to our induction programme. You can provide feedback to your mentor, line manager, or in peer supervision. Welcome to the team!

## **CRF Research Delivery Team**

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### **CRF Senior team**

#### **CRF Director** Andrea Ciprani

Andrea Cipriani is Professor of Psychiatry and an NIHR Research Professor at the Department of Psychiatry, University of Oxford, and Honorary Consultant Psychiatrist at Oxford Health NHS Foundation Trust. Professor Cipriani is currently the Director of the NIHR Oxford cognitive health Clinical Research Facility, Lead of the Digital and Informatics Theme of the Oxford Health Biomedical Research Centre and the Editor in Chief of Evidence-Based Mental Health (<https://ebmh.bmj.com/>).

His main interest in psychiatry is evidence-based mental health and his research focuses on the evaluation of treatments in psychiatry, mainly major depression, bipolar disorder and schizophrenia. His research in the methodology of evidence synthesis has now a specific focus on individual patient data network meta-analysis and data science, trying to assess the validity, breadth, structure and interpretation of innovative statistical and machine learning approaches to better inform the decision-making process between patients and clinicians and personalise treatment indications in routine clinical care.

On a broader basis, the Consultants take responsibility for the medical planning of studies proposed for the CRF, attending feasibility and set up meetings, and advising on the medical procedures and safeguards required for high intensity studies. In recent studies these have included intranasal administration, use of controlled drugs, intravenous administration, lumbar punctures and skin biopsies. Broader medical issues requiring further consultation are discussed with the Clinical Lead for the CRF and with the Director of the CRF and of R&D Oxford Health NHS Foundation Trust. The Consultants also have a regular clinical commitment in the specialist Bipolar Disorder research clinic and/or specialist Treatment Resistant Depression clinic, with assessment and follow-up of patients in the clinic, and teaching of trainee psychiatrists and medical students. They operate a within-hours rota for clinical issues arising with these patients. An out-of-hours rota is also provided by the Consultants/Specialty doctors where required by specific research studies, for urgent medical issues including emergency unblinding.

#### **CRF Co-director/Head of Research Delivery** Catherine Henshall

The Head of Research Delivery is responsible for leading the strategic direction and oversight of the mental health and community research delivery teams across OHFT. This involves working closely with the NIHR and CRN to ensure that their requirements are met and promoting greater efficiency and effectiveness across the teams in terms of study set-up, recruitment, delivery, research engagement and quality assurance. The role includes the line management of the Research Delivery Manager, Research Engagement Manager and Quality Assurance Manager. As part of the R&D Senior Management Team (SMT), the Head of Research Delivery works closely with SMT members to ensure that research delivery aligns with the overarching R&D, Nursing and Trust strategies for research. The postholder is also an NIHR 70@70 Senior Nurse Research Leader, responsible for building the research capacity of nurses at a local and national level. They are also involved in a number of studies as principal and co-investigator in their clinical academic role across OHFT and Oxford Brookes University.

**CRF Deputy Director / Clinical Lead - Katherine Smith**

The Clinical Lead who is also a Consultant Psychiatrist works with the team to ensure clinical research is conducted safely for both participants and staff to a high standard. This role includes working with the Research Delivery Manager, CRF Manager and the Lead Research Nurse to respond to research demands to broaden capability (e.g., lumbar punctures). The Clinical Lead who is also the Deputy Director of the CRF is part of the CRF Senior Management Team (SMT). SMT activity includes overseeing staff skill mix, managing demand for new studies and developing the CRF Strategy in line with the NIHR CRF award and the Oxford Health BRC.

**CRF Manager - Claudia Hurducas**

The CRF Manager provides operational oversight, leadership, and expertise to the CRF team, including the CRF team leader. The CRF Manager is part of the CRF Senior Management Team (SMT) but also Research & Development SMT. They ensure communication between team and Senior Management team is streamlined and they help to facilitate this. The post holder holds responsibility for CRF reporting to fund holders (for example oversight of CRF annual reporting to the NIHR). They also hold strategic oversight for the CRF's vision and represent the CRF in conversations with key stakeholders (NIHR, BRC, R&D, etc.).

**Finance Manager – Bill Wells**

**CRF Executive team**

**CRF Team Leader/Senior Research Nurse – Amanda Colston**

The CRF Team Leader provides clinical leadership and expertise, overseeing the resource planning of the unit (making 'it work' on a day to day basis). They make sure that studies are conducted in compliance with research legislation and protocols and that recruitment targets are met on time, working alongside the research teams to help facilitate this. The post holder holds line management responsibility for staff on the unit. Workforce development is a key role; this includes leading on training, supervision and appraisals as well as managing and monitoring performance.

**Specialty Doctors – Caroline Zangani, Edoardo Ostinelli (works at the CRF on Thursdays only)**

The Specialty Doctor also provides medical input to the CRF and is involved in all the daily medical tasks required to perform high intensity clinical research studies in psychiatry. On a day to day basis this is represented by planned tasks including recruitment of research participants, explaining study procedures (especially medical ones) and obtaining informed consent, assessing capacity to consent to studies, assessing the medical history of both physical and psychiatric disorder, physical examinations (including neurological), review of results of investigations, conducting standardised interviews and assessments, and assessing eligibility or not to proceed in studies. The Specialty Doctor is also involved in discussions about medical planning on the CRF, with the support of the Consultant Psychiatrists. He/she provides medical cover for research studies including planned assessments and emergency assessments as required. He/she also participates in the out of hours on-call rota covering clinical research studies on the CRF. Line management and supervision for the Specialty doctor is provided by one of the Honorary Consultant Psychiatrists.



**Psychiatrist** - Edoardo Giuseppe Ostinelli

Senior Researcher & Evidence Synthesis Expert, Oxford Precision Psychiatry Lab, Department of Psychiatry, University of Oxford, DPhil Candidate, Department of Psychiatry, University of Oxford, CRF Medic, NIHR Oxford cognitive health Clinical Research Facility, Oxford Health NHS Foundation Trust, Oxford, Honorary Consultant Psychiatrist, Oxford Health NHS Foundation Trust, Oxford

**Pharmacist** - Joanne Galloway

**CRF Delivery team**

**Administrator** – Val Pulley (senior administrator)

The administrator's role is essential to the CRF team. The administrator supports the day-to-day running of the unit. This includes booking rooms, staff and equipment for different research groups and ensuring the smooth running of these bookings. These bookings are scheduled on a web-based management system (CRFManager®). A CRF folder is maintained on the Trust's network folder (G: drive) by the administrator – this holds electronic copies of policies, procedures, audits, and study specific information.

**Research Admin Assistant** - Sugandika Gajaweera

**Research Nurses** – Balaji Rajendran, Abigail Stewart, Sam Agyapong, Alison Newton (PT), Jesse Usman

The main task of the research nurse is the day-to-day leadership of studies, ensuring that studies are conducted in compliance with all legislation and protocols and that recruitment targets are met. They also actively undertake assessments and procedures during study visits according to the study protocol. Research nurses promote the studies to different services and clinical teams and liaise with patient and carer groups and charitable organisations. Research nurses also work together with the medics to manage the recruitment of participants for research studies. The research nurses work under the overall direction of the lead research nurse manager. All Research Nurses receive regular supervision from a senior member of the research team. The band 6 nurses rotate coordinating the shift and day to day running of the CRF and have additional responsibilities such as the supervision of staff.

**Research Facilitator** – Rebecca Smith

Research Facilitators are involved in many of the day-to-day activities within the CRF. A key part of their role is the organisation and completion of participant visits, including study assessments and procedures. Research Practitioners actively undertake assessments and procedures during study visits according to the study protocol. They will assist with data collection and are responsible for completing paperwork and often recording data electronically. Research Facilitators receive regular supervision from a senior member of the research team.

**Research Assistants** - Rachel Delahay, Wendy Hurst

Research Assistants support research protocol delivery tasks including recruitment, education and monitoring of trial participants, collection, and processing of biological samples (including blood and tissue samples) and accurate data collection and management. Research Assistants are required to

develop and maintain a working knowledge of trial protocols and their application in practice, enabling them to deliver research activity in compliance with the local, national, and international research regulations.

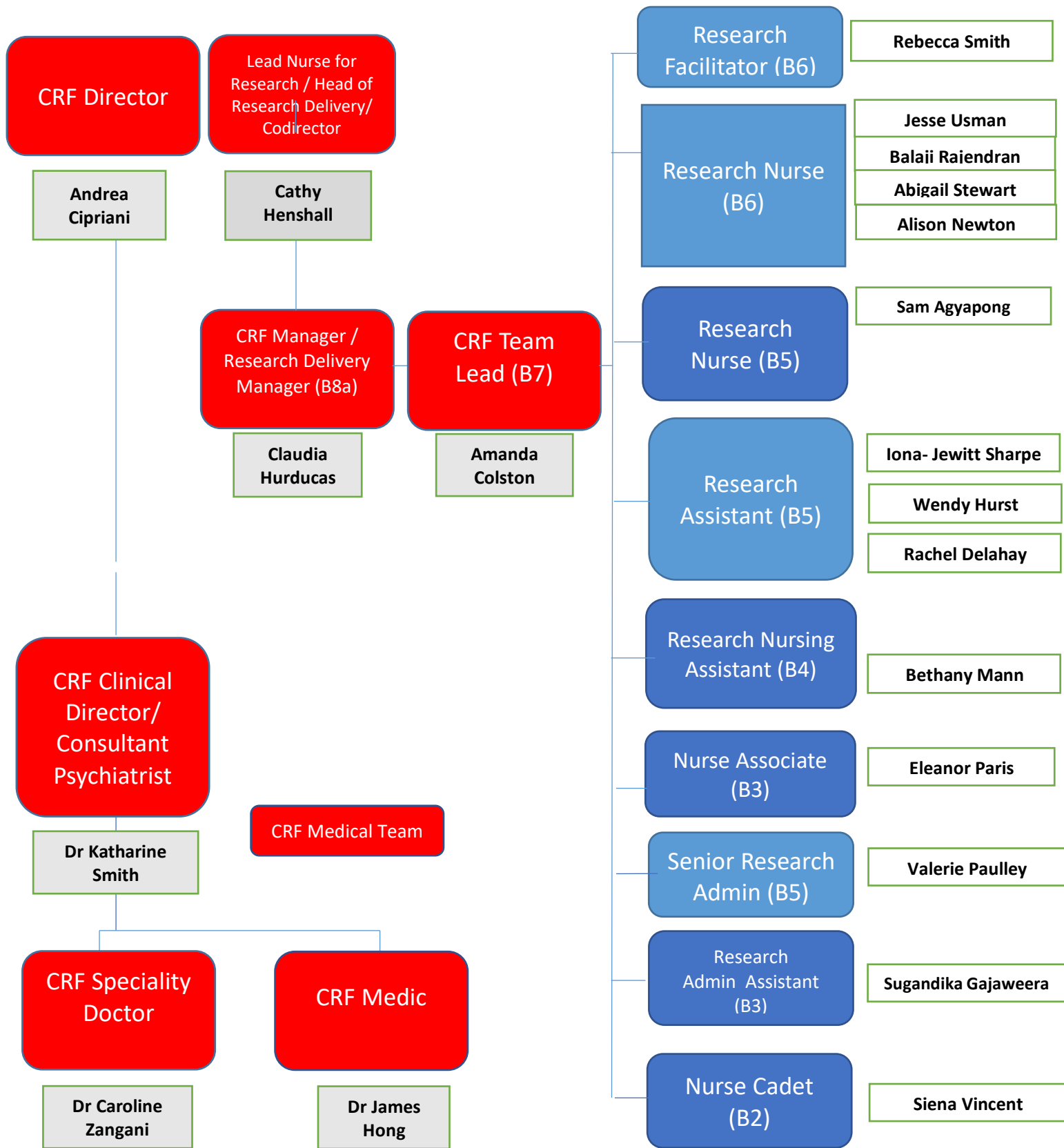
**Research Nursing assistant - Beth Mann**

Research Nursing assistants support research protocol delivery tasks including recruitment, information and monitoring of study participants, collection, and processing of biological samples (including blood and tissue samples) and accurate data collection and management, under the supervision of a Clinical Research Nurse. The role also requires the post-holder to develop and maintain a working knowledge of study protocols and their application in practice, enabling them to deliver research activity in compliance with the local, national, and international research regulations. This post would suit someone with a background in healthcare. Clinical experience within the field of mental health is desirable, but not essential.

**Nursing Associate Trainee (NAT) – Eleanor Paris**

**Nurse Cadet – Siena Vincent**

The Thames Valley Nurse Cadets program focuses on supporting 16- to 19-year-olds begin their career in healthcare by completing a two-year Senior Healthcare Support Worker apprenticeship. The apprenticeship offers learning opportunities with an active role in the work environment as a band 2 support worker. The two-year senior healthcare support worker apprenticeship (Nurse Cadets) consists of four days working and one day of studying per week.



\*CRF Team Lead Nurse provides clinical supervision to CRF core staff.

## Induction Tasks

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An induction checklist will be prepared for you which provides a day-to-day, week-by-week summary of the activities that you are expected to cover during your induction. Make sure you familiarise yourself with the tasks proposed and discuss with your mentor and the CRF team any extra learning opportunities available.

You will meet our administrator in order to complete the following administrative tasks:

- Trust computer access and log-in details
- Access to G-Drive
- Help with any administrative tasks as required

### Standard Operating Procedures

Standard Operating Procedures (SOPs) are defined in the ICH-GCP guidelines as ‘detailed written instructions to achieve uniformity of the performance of a specific function’. The aim of SOPs is to ensure that any procedures or processes within the facility are undertaken consistently. Study-specific SOPs ensure that any procedures performed as part of the research trial are done to a consistently high standard, thus enhancing the quality of the data produced.

All students should make themselves aware of the SOPs for the CRF on commencement in post. A folder with all Standard Operating Procedures (SOPs) for the CRF can be found at Reception office in the main filing cupboard. Digital copies of these can be found on G-Drive: *Oxfordshire>Clinical Research Unit>Standard Operating Procedures>CRF SOPs Final versions*. Please make sure you sign the hard copy of every SOP after familiarising yourself with the procedures. Any new or amended SOPs will be circulated to staff as and when necessary.

## Training

Training is suggested for your placement period. The proposed schedule is a guide for completing your required training and it can be completed in accordance with your own learning needs, especially if additional learning opportunities become available. Please make sure your practice supervisor is aware of any changes to your training schedule.

Training can take several forms. It can refer to the NIHR mandatory training, it may be part of the Oxford Health NHS Foundation Trust training, it can be related to CRF operational processes, it may involve shadowing different professionals for different tasks during study visits, or it may be part of study-specific training requirements. Below you will find a table with information on the various accounts you will need to set up as part of your induction, and how to access training.

It is up to the student to keep their own training file.

**IT IS ADVISABLE YOU USE A PASSWORD LOCKER TO STORE YOUR USERNAMES AND PASSWORDS FOR ALL YOUR ACCOUNTS**



## **Shift Coordination**

A Band 6 member of CRF staff coordinates each shift on a daily rotational basis. The shift coordinator has responsibility for leading the morning handover meeting, ensuring that all visits for that day have been allocated, and they are the first port of call for any queries within the team that arise during that particular shift. The coordinator does not have to complete all daily tasks, they can delegate any of these to other appropriately trained team members, but they are ultimately responsible for ensuring that all necessary tasks have been completed by the end of the day. Please refer to the coordination SOP for more details.

## **CRF Checks**

Environmental, health and safety checks are carried out by CRF staff on the unit on both a daily and a weekly rotation and as a student you will have the opportunity to contribute to these. These checks are to ensure that the environment remains safe and conducive to research. Environmental checks are carried out to monitor the temperature of fridges and freezers on the unit, where samples and equipment are stored. Resuscitation equipment and emergency medication is checked daily, and fire alarms are tested each week. A file can be found in the Staff Office containing all the necessary forms to conduct the environmental checks. When completed, copies of these forms are uploaded to the CRF G: Drive by the team administrator. These are then available for study teams and sponsors if necessary.

Daily checks – Diary and CRF Manager, AED equipment, contents of the green bag, expiry on blue and red emergency medication boxes, glucose monitor calibration, samples to be moved, blood results to be looked up and checked, Tutela temperature monitoring, stock check/e-procurement, generic email inbox.

Weekly checks – emergency and stock drugs log, fire alarm test, sharps bins, shower room (twice weekly), pit alarms, washing of lab coats, cleaning of all equipment in store cupboard, thorough clean on the unit, waiting room coffee machine clean, contact referrals.

Monthly checks – Fire equipment and escape routes, spare resuscitation equipment, oxygen cylinders, downloading of temperature records for past month (Lab fridge, -20 Freezer, -80 Freezer, Ambient temperature; Pharmacy fridge, -20 Freezer, -80 Freezer and Ambient temperature), expiry dates on consumables, stock check for coffee machine, first aid and first aid spares contents checked.

## **CRF Meetings**

The CRF hold regular meetings that staff are expected to attend. These include:

- **Morning Handover Meeting:** Held daily at 9am and chaired by the shift coordinator for that day; here tasks are allocated, and any supervision/meetings/training or other absences are highlighted.
- **Research Coordinators Meeting:** At 2.30pm every Wednesday, except for the last week of the month where it is held on Friday; here staff give feedback and updates in relation to the progress of ongoing studies on the unit.
- **Team meeting:** Held on the first Tuesday of every month at 1pm. This is a forum for CRF staff to feedback on lead role developments, discuss upcoming training, share ideas, plan future work, and delegate duties.
- **Peer supervision:** Held monthly for CRF staff to discuss any clinical issues or skills requirements which have arisen over the past month.

## **Bipolar Disorder and Treatment-Resistant Depression Research Clinics**

Every Thursday both the Bipolar Disorder and Treatment-Resistant Depression Research Clinics are held at the CRF. These are specialist clinics for individuals potentially meeting the criteria for a diagnosis of either Bipolar Disorder or

Treatment-Resistant Depression. The psychiatrists running the clinics will complete a full assessment of the patient's current presentation and take a psychiatric history to establish which of the available treatment options best suits the individual concerned. As these are research clinics the core focus is to recruit patients into our treatment-based studies, and thus offer a new approach for those patients who have not previously benefitted from the treatments they have been provided, whilst simultaneously gathering data to measure the effectiveness of current treatments and inform the development of new treatments.

At 8:45am each Thursday a meeting is held to discuss referrals that have been made to the clinic and consider their suitability. As part of your induction, it is beneficial to attend at least one of these meetings, and when possible, shadow the assessments that follow. There will often be medical students present to shadow the clinics, and as their education takes precedence it may take multiple attempts before gaining the opportunity to sit in on a clinic assessment.

New patients will need to be registered on True Colours, an online system which asks patients to complete specific questionnaires in relation to their mental health and wellbeing, and subsequently plots their scores onto graphs which the clinicians can then review. CRF clinical staff contact all new referrals prior to their appointment, to inform them about their referral and the clinic, with a view to registering them on the True Colours system with their consent. A member of CRF staff will train you in how to do this, and a useful guide for support in this process can be found on G-drive: *Oxfordshire>Clinical Research Unit>Standard Operating Procedures>Guides>True Colours Guide*

At each new patient assessment, the CRF clinical team initiates the clinic appointment by completing a physical health screening. Patients are then asked to complete a series of self-report questionnaires via True Colours prior to seeing a doctor for assessment.

### **Study-specific Training, Participant Information Sheets and Protocols**

The CRF hosts a diversity of studies and there will be an opportunity to shadow and observe these. Speak with the individual study co-ordinators to schedule in times. Training needs are often study-specific and make be provided informally or formally, internally, or externally. You may only work independently on a study once you are considered to have reached competence. At this point, your name will be added to the delegation log and authorised by the Principal Investigator (PI).

When working on studies, CRF staff are often responsible for conducting tests, assessments, and questionnaires, and for collecting samples which may then need to be processed in the lab. Staff are also responsible for accurately documenting information, much of which is entered onto study-specific electronic systems.

Each study has an accompanying Patient Information Sheet (PIS) which provides a relatively succinct but cohesive summary. This sheet provides a good introduction to the study and is useful to read in the first instance. The Study Protocol is a far more comprehensive document, and all staff should be familiar with their own study's Protocol.

Study-specific documents can be found on G-drive: *Oxfordshire>Clinical Research Unit>Trial Master Files*.

### **Lead roles**

Each team member on the CRF may have a lead role and you would be welcome to speak to and/or spend time with the staff member as wished. This is an area of work which they lead on for the team, ensuring that practice standards are met and maintained, and that service developments and improvements can be achieved. Lead role holders' feedback to both the wider team and management on these areas. The tasks relating to these roles can be delegated to, or taken on by, other staff members, but the lead for that role holds ultimate responsibility. Below is a list of the current CRF lead roles:

- PPI (Patient and Public Engagement)
- Quality Assurance
- Computer Systems (Including Tutela, CRF Manager, G-Drive, eProcurement)
- Clinical Equipment
- Clinical Skills (Including Resuscitation)
- Student Placements
- Participant Recruitment (including Treatment Resistant Depression and Bipolar Disorder Clinics)
- Study Set-up
- Infection Prevention & Control
- Fire Safety
- Social Media
- Education
- First Aid

Due to collaboration with various infrastructures (Oxford University, Brookes University, etc.) there will be opportunities for interested staff to get involved in writing pieces for publication, undertaking systematic reviews, developing, and presenting conference abstracts, etc.



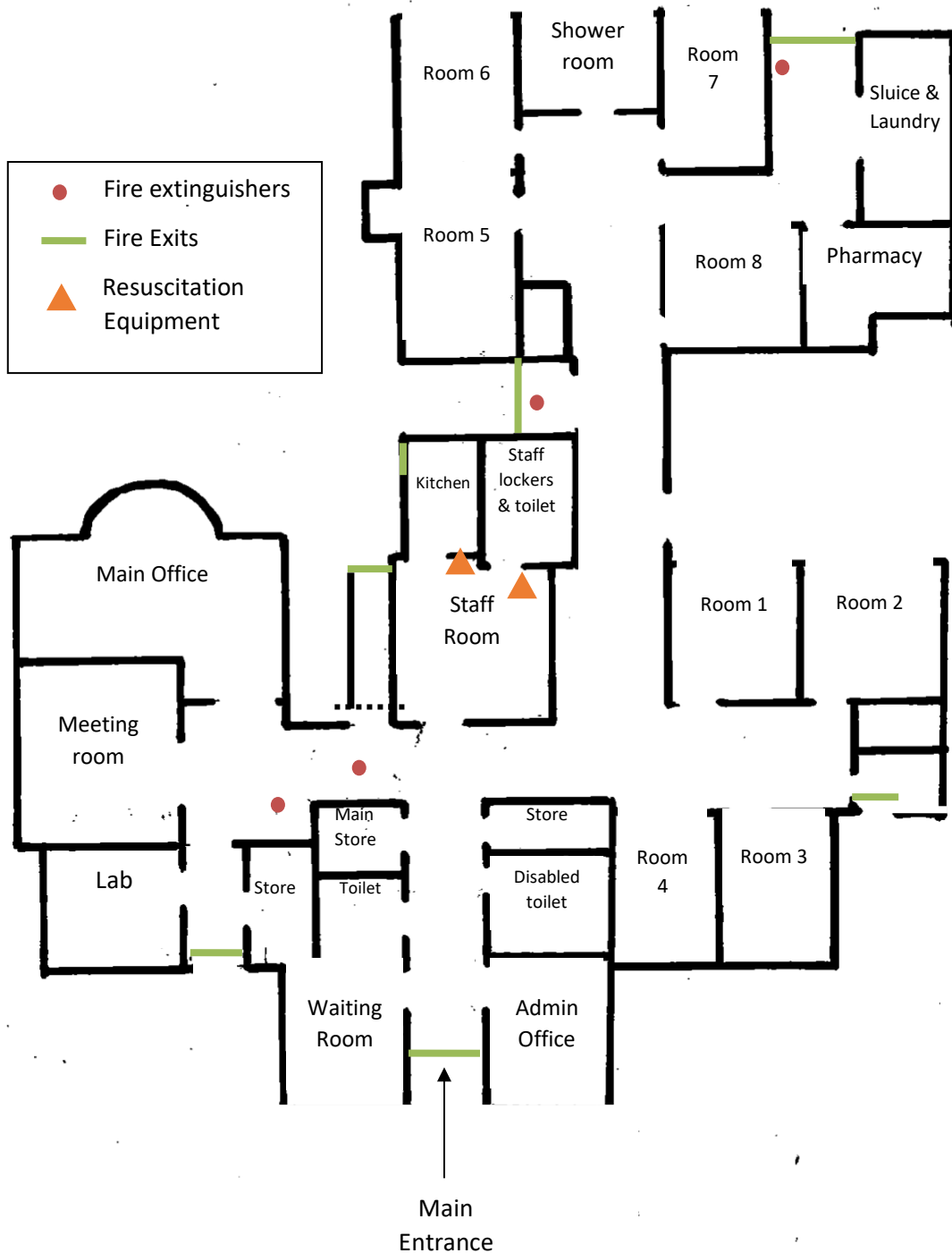
We have put this timetable together for your first week to help with your orientation, but it is flexible. Please feel free to swap things around according to your learning needs but most of the things included should be a useful start to your placement.

Things to do: NIHR – GCP, informed consent, shadow visits, meet team, show round, provide docs, answer questions,

	<b>Monday</b>	<b>Tuesday</b>	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>
Suggested activities/learning  Joint coordination with a B6 member of staff when confident	Meet the team!  ✓ Register GCP takes about 1/2hours  ✓ Informed consent training   STUDY VISIT AM/PM	Start to think about where to visit and arrange     STUDY VISIT AM/PM	STUDY VISIT AM/PM	STUDY VISIT AM/PM and Bipolar clinics and Treatment Resistant Depression clinics	STUDY VISIT AM/PM
Meetings available	9am morning handover 10 mins (daily) Nurses meeting (1 <sup>st</sup> Monday of the month)	9am morning handover 10 mins	9am morning handover 10 mins 2-3pm coordinators meeting (weekly)	9am morning handover 10 mins	9am morning handover 10 mins
CRF daily activities	Medication check Check resus bag	Check resus bag	Check resus bag	Weekly clean Check resus bag	Check resus bag
Other opportunities	<i>Set targets for the week</i>			R & D updates (not every week) CRF monthly meeting 1-2pm	Lab lunches <i>Catch up meeting</i>

## Working in the CRF

Please make yourself familiar with the layout of the unit.  
Fire extinguishers and fire exits are marked on the map below.  
Resuscitation equipment is found in the staff office, directly opposite the door, and emergency drug boxes are on the wall and shelf, as marked on the map below.  
Please be aware that the sluice, pharmacy, lab and staff room are staff only areas.



**Glossary of terms**

ADR – Adverse Drug Reaction

AE – Adverse Event

AED - Automated External Defibrillator

AR – Adverse Reaction

BLS – Basic Life Support

BPS – British Psychological Society

BRC – Biomedical Research Centre

BRU – Biomedical Research Unit

CDA – Confidentiality Disclosure Agreement

CDR – Clinical Dementia Rating

CI – Chief Investigator

CPD – Continued Professional Development

CPR - Cardiopulmonary Resuscitation

CQC – Care Quality Commission

CRA – Clinical Research Associate (Monitor)

CRF - Case Report Form

CRFs – Clinical Research Facilities

CRN TV+SM – Clinical Research Network Thames Valley and South Midlands

CRNCC - Clinical Research Network Coordinating Centre

CSAG – Clinical Studies Advisory Group

CTA – Clinical Trials Agreement

CTIMP – Clinical Trial of an Investigational Medicinal Product

CTUs – Clinical Trials Units

CV – Curriculum Vitae

DeNDRon – Dementias and Neurodegenerative Diseases Research Network

DPA – Data Protection Act

ECG – Electrocardiogram

EPAD - European Prevention of Alzheimer’s Dementia

FAQs – Frequently Asked Questions

FMRIB - Oxford Centre for Functional MRI of the Brain

GCP – Good Clinical Practice

GCS – Glasgow Coma Scale

GMC – General Medical Council

HRA – Health Research Authority

HTA – Human Tissue Act/Authority

ICF – Informed Consent Form

ICH – International Conference on Harmonisation

IEC – Independent Ethics Committee

ILS – Immediate Life Support

IM – Investigator Meeting

IMP – Investigational Medicinal Product

IRAS – Integrated Research Application System

ISF – Investigator Site File

LP – Lumbar Puncture

MCA – Mental Capacity Act

MHA – Mental Health Act

MEG - Magnetoencephalography

MfHU – Medicines for Human Use

MHRA – Medicines and Healthcare Products Regulatory Agency

MHRN – Mental Health Research Network

MRC – Medical Research Council

MRI - Magnetic Resonance Imaging

NDA – Non-Disclosure Agreement

NEWS – National Early Warning Score

NHS – National Health Service

NICE – National Institute for health and Clinical Excellence

NIHR – National Insistute of Health Research

NK – Not Known

NMC – Nursing and Midwifery Council

NRES – National Research Ethics Service

NTAD - New Therapeutics in Alzheimer’s Disease

OHBA – Oxford Centre for Human Brain Activity

OHFT – Oxford Health Foundation Trust

OHSRC – Oxford Health Services Research Committee

OTR – Online Training Records

OUH – Oxford University Hospitals

OxCAMs - The Oxford Calcium Channel Antagonism Study

PALS - Patient Advice and Liaison Service

PCPIE – Patient, Carer, Public Involvement and Engagement

PDR – Personal Development Review

PET – Positron Emission tomography

PI – Principal Investigator

PIS – Participant Information Sheet

PPI – Patient and Public Involvement

QA – Quality Assurance

QC – Quality Control

RA – Research Assistant

R&D – Research and Development

RCT – Randomised Controlled Trial

REC – Research Ethics Committee

RGF – Research Governance Framework

SAE – Severe Adverse Event

SAR – Serious Adverse Reaction

SIV – Site Initiation Visit

SOP – Standard Operating Procedure

SSI – Site Specific Information

SUSAR – Suspected Unexpected Serious Adverse Reaction

TMF – Trial Master File

TRD – Treatment Resistant Depression

-END-