Standard Operating Procedure

APPLYING FOR USE OF UHBW CLINICAL RESEARCH FACILITY

SETTING Trustwide

AUDIENCE All staff including those employed outside of University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) wishing to request use of the UHBW Clinical Research Facility (CRF)

ISSUE Use of UHBW space for research and non-research purposes.

Document History

SOP number	SOP	**SOP Version**	1.0
Effective Date	25/FEB/2021	**Review Date**	25/FEB/2023

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
N/A	V1.0	30/NOV/2020	25/02/2021	Jess Bisset Elinor Griffiths	Diana Benton on behalf of Trust Research Group

Version Number	Reason for change
Original V1.0	N/A

1. Introduction

On the 1st January 2021 ownership of the University of Bristol Clinical Research Imaging Centre (CRIC) building located at 60 St Michael´s Hill, Bristol, BS2 8DX was transferred back to UHBW. The Research & Innovation (R&I) Department in Trust Services Division is responsible for use of the rooms in the sleep study suite and clinical investigation suite and all equipment (except the MR scanner). The responsibility for the MR scanner and associated rooms resides with the Specialised Services Division and not R&I. The space utilised by R&I will be referred to as the Clinical Research Facility (CRF). The *CRF management structure is available on request.*

Use of the building is primarily for research with priority given to delivery of National Institute for Health Research (NIHR) Urgent Public Health (UPH) badged COVID-19 vaccine and testing studies and experimental medicine translational research. During times when UPH badged

COVID-19 research is not active, the priority for use by other commercial and non commercial funded NIHR-badged research will be raised. Prioritisation decisions on room usage will be made by the UHBW Director of Research and R&I via the CRF Management Group (CMG). On occasion however the space may also be requested for clinical use if not needed for research purposes.

2. Purpose

This SOP sets out the process of requesting and approving use of the CRF, and the conditions of use.

3. Scope

In Scope: All requests for use of the CRF space.
Out of scope: Research conducted at other locations at UHBW. Use of the MR scanner which is the responsibility of the Specialised Services Division.

4. Responsibilities

- The CRF Management Group (CMG) is responsible for reviewing and authorising requests for use, and for oversight of use of the CRF.

- Researchers are responsible for ensuring any research carried out within the CRF is done so in accordance with applicable approvals (e.g. Health Research Authority/Research Ethics Committee etc.), within the scope of what was agreed in the TMPL_100 Use of CRF Form, this SOP and any applicable UHBW policies.

- Other users of the CRF space (i.e. for clinical use) are responsible for ensuring use is in accordance with agreement from the CMG, this SOP and any applicable UHBW policies.

5. Abbreviations and Definitions

Abbreviations	
CRF	Clinical Research Facility
CMG	CRF Management Group
CRIC	Clinical Research & Imaging Centre
HRA	Health Research Authority
MA	Management Assistant
NIHR	National Institute for Health Research
REC	Research Ethics Committee
R & I	Research and Innovation
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust
UPH	Urgent Public Health

Definitions	
Out of hours	5.00pm-9.00am and includes weekends (all hours of Saturday and Sunday).

6. Procedure

6.1 Requesting use of the CRF

If personnel first wish to discuss what space is available, their proposed research (if applicable) and potential suitability they can email CRF@uhbw.nhs.uk

All potential users will be required to complete TMPL_100 Use of CRF Form and will email it to CRF@uhbw.nhs.uk. If requested use is for a research study the study protocol, any applicable approvals and supporting documentation must also be emailed for consideration. Charges will be applied for use of the space unless agreed otherwise. Details of the cost of hire can be found on TMPL_100 Use of CRF Form

Organisations who wish to use the CRF without involvement of UHBW staff or patients (and therefore where UHBW will not be set up as a research site) will be required to complete a Service Level Agreement. This will be discussed with the organisation on a case by case basis and where appropriate overarching agreements may be put in place to cover multiple uses of the CRF. The CMG will arrange and store all applicable agreements.

6.2 Review and authorisation of request

On receipt of the request form into the CRF@uhbw.nhs.uk inbox, the CRF Management Assistant (MA) will review the form for completeness. If any sections are missing/ further information is required they will liaise with the personnel making the request to fully complete the form or to arrange a call to discuss any queries.

The completed form will be submitted to the CMG who usually meet weekly. The group will review the request alongside the existing space commitments in the CRF. Where there are competing requests for the space, decisions will be made based on the following priorities and in consultation with the Director of Research:

i. Delivery of NIHR Urgent Public Health badged COVID-19 vaccine and testing research studies
ii. Experimental medicine research studies
iii. Clinical out-patient activities, providing there is sufficient capacity and they do not displace the above priority work

The aim will be to accommodate early phase experimental translational research studies alongside the Urgent Public Health studies whenever possible. During times when UPH badged COVID-19 research is not active, the priority for use by other later stage commercial and non-commercial funded NIHR-badged research will be discussed.

If any clarifications are required, a member of the CMG will liaise directly with the personnel submitting the request.

If approved, a member of the CRF Management Group will complete *TMPL_101 Agreement for Use of CRF* and return it to the user. It will act as agreement for use of the space. This agreement will however be conditional on:

(i) All required approvals for research (e.g. HRA, REC etc.) being in place prior to any commencement of the research and for its duration
(ii) Any changes to timelines being resubmitted to the group for review and approval

(iii) Only the requested space being used and for the purpose it was originally agreed with due respect given to any others also using the space
(iv) Funding being provided for use of the CRF as per any agreed invoicing arrangements
(v) A building induction being completed (if not previously carried out) for all relevant staff.

As it may not be feasible to know the exact dates the CRF will be required at the time of submitting the request, the process described above will be to approve the use of the CRF in principle for the research study/clinic use within the provisional timescales. Once the use is approved, the rooms will be booked as per 6.4 and 6.5 below.

6.3 Filing of documents

The MA will save all correspondence and documents on the R&I shared drive.

6.4 Booking the rooms using Calpendo

Once the CMG has approved the request the MA will notify the user via email that they are now authorised to book rooms at the CRF. This notification email will include details for logging onto the booking system Calpendo as a user with a unique project code. Users will request particular time slots and locations by booking into the Calpendo system. Bookings will then be confirmed by a member of the CMG, at which point they are firm bookings and the UHBW CRF cancellation policies apply (see section 6.7). All bookings made under the project code will be monitored to ensure that they are in accordance with the agreed request form. Bookings can only be taken when a user has registered themselves and their project on the booking system.

Where appropriate a temporary swipe card to the CRF building (or access activated on an existing UHBW swipe card) will be arranged.

6.5 Advance booking limit

In order to accommodate use of the CRF effectively an advance booking limit is in place which is 6 months.

6.6 UHBW policies and procedures

Any personnel wishing to use the CRF as a UHBW facility must follow applicable UHBW policies and procedures. On authorisation of the request for use as per 6.2, *TMPL_101 Agreement for Use of CRF* will be provided listing applicable UHBW policies and procedures to read. Users will be required to sign this to indicate they have read and will abide by applicable procedures.

For external staff (i.e. those without a related UHBW contract) applicable policies and procedures will be provided.

6. 7 Cancellations

Cancelled bookings may be chargeable. For any project, the first ‘chargeable’ cancellation will be overlooked, but subsequent cancellations may be charged. Researchers failing to arrive or arriving late may also be subject to a charge. Under exceptional circumstances cancellation charges may be waived. If a charge has been applied and a waiver is requested, the personnel will be required to email CRF@uhbw.nhs.uk for the CMG to consider.

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP 007 Research Training*.

REFERENCES	N/A
RELATED DOCUMENTS AND PAGES	TMPL_100 Use of CRF request form TMPL_101 Agreement to use of CRF SOP_007 Research Training
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Innovation Department via CRF@uhbw.nhw.uk