NIHR | King's Clinical Research Facility

Room Booking and the Registration of Study Subjects in the King's Clinical Research Facility

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October 2015	1. Amended title of SOP 2. Amendments to all sections to reflect current CRF practice 3. Section 5.7: addition of a CRF Registration Form	E.Giemza
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	5. Section 5.10: updated information on the provision of participant wristbands 6. Minor amendments to text throughout document for clarity	
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1.0 Background

1.1. The NIHR / Wellcome Trust King's Clinical Research Facility (CRF) is a specialist unit for experimental and translational medicine and provides specialist facilities for researchers wishing to conduct clinical research. Applicants for both commercial and non-commercial studies are eligible to apply to use the CRF. Commercial studies are mainly conducted within the Clinical Trials Facility (CTF) and non-commercial studies are mainly conducted within the Experimental Medicine Facility (EMF).

1.2. All applications to conduct a study within the CRF are submitted online via the King's CRF website and once the application paperwork is complete, sent for approval (see *CRF-ADMG-SOP-1: The Application and Approval Process for Studies in the King's CRF*).

1.3. Once the study has been authorised to take place in the CRF, and all other necessary approvals are in place, researchers can book space in the CRF to conduct their study assessments.

1.4. There are two databases onto which study subjects are registered when participating in a study in the CRF. One is the CRFManager® database, which is the CRF's study management and scheduling system, and the other is PiMS, the patient administration system for King's College Hospital NHS Foundation Trust (KCH). Any subjects participating on studies, who have not previously been registered onto PiMS, need to be registered in order to generate a KCH number for them.

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the process for the booking of rooms in the CRF and also the process for registering study subjects onto CRFManager® and PiMS.

3.0 Scope

3.1 This SOP applies to all core CRF staff who may be involved in making bookings and registering study subjects. This includes the CRF Receptionist, CRF Administrator and CRF Data Analyst, but also other team members who are required to make bookings and register study subjects in the absence of the administrative team (such as the clinical staff, CRF Manager and CRF Quality Assurance Manager).

3.2 This SOP also applies to all Principal Investigators, and their study teams, who will be booking and using the resources / facilities within the CRF.

3.3 The CRF encompasses the Clinical Trials Facility (CTF), the Experimental Medicine Facility (EMF) and the Cell Therapy Unit (CTU). CRF SOPs apply to the CTF and EMF only and staff working in these areas should work to all relevant CRF SOPs. The CTU will continue to control and use its own policies and SOPs to ensure compliance with Good Manufacturing Practice (GMP).

4.0 Responsibilities

4.1 Principal Investigators and members of their study team are responsible for providing the information needed to book rooms and register subjects in the CRF.

4.2 The CRF Administrator or CRF Receptionist, or their nominated delegate, is responsible for ensuring that study subjects are registered as required onto CRFManager® and PiMS in a timely manner and that the information entered is accurate.

5.0 Procedure

5.1 Once a study has been approved and authorised, it will be allocated a 'K' number on CRFManager®. When the study status is showing as 'Active', room bookings in the CRF can commence. All booking requests should be sent by the study team to kingscrf@kcl.ac.uk.

5.2 The study team should provide the following when booking a room:

- Name of study
- Date and time of booking
- Duration of booking
- Preferred location (ie: EMF or CTF)
- Type of facility required (eg: clinical room, research chair, interview room)
- Subject/screening ID number or the subject's initials
- Subject's date-of-birth (if known)
- The visit number (eg: Screening, Visit 1, Follow-up)
- Whether the subject is a patient or a healthy volunteer

5.3 The booking will be made by the Receptionist or Administrator, or their nominated delegate, on CRFManager®. No identifiable subject information must be entered onto the database in order to comply with data protection legislation and the KCH Information Governance Policy. The subject's study/screening ID number or their initials should be used, plus the subject's date-of-birth, if known.

5.4 **CRFManager® registration and booking process:**

5.4.1 Room/resource bookings should be made in the 'Scheduling' section of CRFManager®, under 'Clinical Accommodation' at the top of the Scheduling page, and by selecting CTF or EMF from the drop-down box. It is then possible to select the facility/resource requested and book it for the time requested. This can then be edited (by selecting 'Edit booking') to enter all of the required details. Each patient is registered under the relevant study's room/resource booking.

5.4.2 The patient is added to the booking by selecting 'Book patient', with the type of visit they are attending and the duration of stay. This is done by selecting the 'find an existing patient' option and selecting 'Next'. (*Please note: if the patient details are not available at this*

stage, a patient must still be added to the booking by selecting 'use a dummy patient' and entering the study name and visit type when requested).

5.4.3 Under 'Identifiers', type in the study name and select 'Search'. Underneath the search results entitled 'CRF System Patient Database', select the correct patient and then click 'Next'. If the patient is not listed, go to step 5.4.6 below.

5.4.4 Enter the name of the study for which the patient is visiting and click 'Next'.

5.4.5 Select the visit type and select 'Next'. Then follow steps 5.4.9 to 5.4.10 below.

5.4.6 If the patient is not listed under 'CRF System Patient Database', select the option 'Add new patient'. Select the 'Anonymous' check-box and enter the study name, an underscore followed by the patient's initials or ID number into the 'Secondary Identifier' data field. The date-of-birth can also be entered in the relevant section if known and then click 'Next'.

5.4.7 Enter the study for which the patient is visiting and select 'Next'.

5.4.8 Select whether the subject is a patient or a healthy volunteer and the type of visit, and select 'Next'.

5.4.9 Check that the duration details of the appointment are correct and amend this if necessary by selecting 'Enter the duration of the visit' and then select 'Next'.

5.4.10 On the 'Resources' page, if a member of core clinical staff is working on a study, enter their name into the text search box, select the result 'Staff' section on the results list and check the allocated time (alter the period of involvement if needed). Once finished, click on 'Next' and then 'Finish' and then 'Close'.

5.4.11 Once done, the allocated patient associated with the room booking will be displayed as *study title_ patient's initials/ID number*.

5.4.12 If it is necessary to book multiple patients for one booking (eg: where two or more patients will be seen during the duration of the booking) or if more than one resource is required for one patient (eg: a clinical room and a research chair), each booking has to be made separately under the same study name. The booking status for these must be entered from the drop-down box as 'Allocated' (yellow) rather than 'Allocated (no overlap)' (red).

5.4.13 To book rooms for an overnight stay, the room booking should be made as usual and then 'Edit booking' should be selected. The duration of the visit can be amended by selecting 'other end date' from the drop-down box. An end date and time should be entered in the boxes below and the booking modified. When allocating a patient to this booking, the duration of the booking should be amended to the correct number of hours (eg: 24 hours) on the 'Patients Appointments' page.

5.4.14 All booking statuses must be completed by the end of each day, indicating the outcome of each appointment. For example, in the event where a patient didn't attend, 'Did not attend' should be chosen or where the patient did attend, 'Completed' should be chosen.

5.5 When a booking has been made, a confirmation e-mail should be sent to the requestor to confirm the booking.

5.6 Bookings for rooms which are no longer required should be cancelled by the study team with at least 24 hours' notice, where possible. This will enable other researchers to be allocated that resource. When this type of cancellation occurs, the booking status 'Cancelled' should be chosen. When a booking is cancelled immediately before, during or after the allocated patient appointment, the booking status 'Late cancellation' should be chosen.

5.7 At the screening visit, **if no bloods are to be taken at the visit**, study subjects will be asked to provide some basic details (including name, gender, date-of-birth, address, telephone number, next-of-kin and GP details) by completing the CRF's Registration Form (*CRF-ADMG-FRM-8*). This also applies to subjects attending once-only visits where bloods are not required. These subjects will not be registered onto PiMS but their details will be available in case of emergency. The Registration Form should be kept securely at the EMF Reception during the visit and safely disposed of as confidential waste following the visit.

5.8 If screened subjects are subsequently included in the study, they will be asked to complete the KCH Registration Form at their next study visit. They should arrive at the CRF in advance of their visit time for this to be completed. They should then be registered on PiMS and this will create a KCH number. If possible, researchers should keep a note of the hospital number once created and it can then be provided by them to the reception staff at each visit.

5.9 Where bloods are required to be taken at screening or at once-only visits, the KCH Registration Form should be completed instead of the CRF Registration Form, as the subject will need to be registered on PiMS at this visit in order to create a KCH number.

5.10 Patient wristbands are not routinely provided for patients attending the CRF. The positive identification of patients receiving medication as part of a study will be achieved by verbal confirmation from the patient of their name and date-of-birth (as per the KCH Medicines Management Policy).

5.10.1 Wristbands will only be issued:

- If deemed necessary for individual patients by a member of the CRF's clinical team
- If requested by the researcher
- If the patient is staying overnight in the EMF or CTF
- If the patient is attending a study visit lasting several hours and wishes to leave the CRF in between study assessments, where permitted by the protocol, (for example, to go to the hospital shop)

5.10.2 Wristbands should be printed from EPR once the patient has been registered on PiMS or hand-written for patients not yet registered on PiMS.

5.11 **PiMS registration process:**

5.11.1 The following information is needed for PiMS: Name and title of subject (including aliases), date-of-birth, gender, address, telephone number, GP details and next-of-kin details.

5.11.2 Referrals must be made for each subject on PiMS. The referral source is the GP and the subject is always referred to the Director of the CRF under the speciality, Clinical Research Facility. Participants can also be admitted under the relevant Professor/Principal Investigator for the study, as requested.

5.11.3 A medical buff note can be created for subjects, if requested.

5.11.4 Labels and a front sheet (which contains the subject's hospital number, contact details etc) can be printed and placed in the first section of the medical buff note.

5.11.5 When admitting subjects on PiMS, they are admitted onto the Clinical Research Facility ward. The admissions type is 'Elective planned' or 'Elective booked'. The management intention is always 'Day Case' unless it is an overnight study. Enter the date and time the subject is being admitted and select 'Admit now'.

5.11.6 When discharging subjects on PiMS, select the 'Ward View' icon on the PiMS toolbar and double-click on the Clinical Research Facility ward. Right-click on the name of the subject and select 'discharge'. The discharge method chosen should be 'clinical advice'; the discharge type is 'treatment completed' and the destination is 'usual place of residence' unless otherwise specified. Enter the date and time of discharge and select 'discharge now'.

5.12 The CRF needs to retain a certain amount of flexibility around the processes described in this SOP, as it hosts a variety of studies and trials with different requirements and different visit types. Thus it may be necessary to amend these processes slightly on a study-by-study basis.

6.0 Related Documents & References

6.1 CRF-ADMG-SOP-1: The Application and Approval Process for Studies in the King's CRF

6.2 CRF-ADMG-FRM-8: CRF Registration Form

6.3 KCH Patient Registration Form

6.4 KCH Information Governance Policy and KCH Medicines Management Policy http://kingsdocs/Pages/Home.aspx

7.0 List of Appendices

N/A

8.0 Approval and sign off

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