Title: Obtaining and maintaining PRB Approval to Conduct Research at ICRF

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Target Audience:	Imperial AHSC Researchers and ICRF staff applying to the PRB.
Location of SOP:	Electronic: EQMS Paper: ICRF Master File, Nurses Station, Staff Lounge
Related SOPs and Policies:	ICRF-POL02 Operational Policy ICRF-OR05 Induction SOP

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Document version numbering

Version	Date	Updated by	Reason for change
1	Jan 2015	Karen Mosley	New SOP (information previously included in the Application Policy and PRB guidance)
2	Mar 2015	Karen Mosley	Minor revisions to reflect changes to PRB process
2.1	May 2015	Karen Mosley	Minor revisions to reflect changes to PRB approval process
2.2	Dec 2016	Karen Mosley	Minor revisions to reflect changes to PRB approval process
3	Feb 2018	Karen Mosley	Minor revisions to reflect changes to PRB approval process and CRF name
4	Feb 2019	Karen Mosley	Changes to terminology, clarifications and addition of ICRF contact per-study.
5	Feb 2020	Athanasia Gravani	Restructure of SOP. Split SOP to create OR34.

1. Background

The ICRF Protocol Review Board (PRB) reviews all studies applying to use the ICRF to ensure that only those studies that are in line with the overall strategy and objectives of the ICRF are approved. For more information refer to the PRB Terms of Reference and the Operational Policy.

2. Purpose

To describe the approval process for investigators who wish to run their study in the ICRF, including applying for and obtaining PRB Green Light approval, maintaining the approval for the duration of the study and booking participants' visits.

Key Points:

- All studies must obtain PRB Green Light approval before participants' visits can be booked.
- All conditions requested by PRB must be met prior to PRB Green Light approval being issued.
- All CTIMP substantial amendments and any significant changes to the PRB approved conditions for any study must be reviewed by PRB.
- The study will be reviewed by PRB on an annual basis until notification of end of study is received.
- PRB approval is subject to adherence to relevant Policies and Procedures and approval may be withdrawn at the discretion of the PRB or ICRF senior management team (SMT).

3. Scope

This SOP applies to anyone who wishes to conduct a study at the ICRF. The tasks described may be undertaken by the Principal Investigator (PI) or their delegate.

4. Obtaining PRB Green Light approval

This section describes the processes involved in applying for and obtaining PRB Green Light approval for a new study.

Before the PRB meeting **Documents to be submitted at least 1 week prior to the meeting date:**	
	Submit the following documents to ICRF General Manager (GM) ▪ Fully completed ICRF application form (see *ICRF-OR09 Form 1*) ▪ Study protocol ▪ Principal Investigator's CV – required for PIs new to ICRF ▪ Investigators Brochure (IB) – required for Phase I CTIMP

At the PRB meeting	
	Attend the PRB meeting to give a brief overview of the study and to discuss any queries. NB: Attendance of the PI is compulsory for Phase I CTIMPs

After PRB meeting: **Outcomes will be sent via email within 5 working days**		
A. Conditional Approval (i.e. study approved to enter the PRB Green Light approval process)	**B. Deferral**	**C. Rejected**
Sign and return a copy of the post-PRB ICRF application form to the ICRF GM to confirm that you accept the conditions requested by PRB.	Address the conditions of deferral and liaise with the ICRF GM to resubmit your study for PRB review at a later date.	No further action.
Your study will be allocated an ICRF study contact for future correspondence. Liaise with them to ensure all conditions requested by PRB are met and keep them informed of the study progress.		*Please note that your study may go ahead elsewhere in the Trust in line with the necessary approvals.*

PRB Green Light
Notify ICRF GM by email when you have addressed all conditions requested by PRB. Once all the conditions have been met, you will receive an email with the study acceptance letter confirming the date that your study has received PRB Green Light (approval). The PRB Green Light is valid for one year from the date of issue. Only after receiving the PRB Green Light approval may you start booking participants' visits using the relevant booking forms (see ICRF-OR09 Form 6 / Form 7). For further details on booking arrangements, please go to section 5.

5. Booking participants' visits

Once PRB Green Light has been issued, you may start booking participant visits. Booking requests are managed on a first-come-first-served basis.

Booking Process	
	Submit a booking request at least 2 working days in advance of the planned participant visit date. The current version of the booking request form (*ICRF-OR09 Form 6 / Form 7*) may be submitted electronically via NHS.net email or handed into reception. Arrange transport to ICRF for your study volunteers if required, unless agreed at PRB that ICRF will do this. *Please note that booking forms will only be accepted if they are completed in full and with at least 2 working days' notice.*

6. Maintaining PRB approval for the duration of the study

Following PRB Green Light, the study will be reviewed by PRB on an annual basis until the end of study notification form is submitted.
The PRB will also review all CTIMP substantial amendments and any significant changes to the PRB approval conditions for any study.

PRB Annual Review	
	Submit the complete study renewal request form (ICRF-OR09 Fm11) to ICRF GM (or delegate) before the anniversary of the PRB Green Light approval date. *Please note that your study team's training records will be reviewed as part of the PRB annual review so please ensure these are up-to-date.*

Study amendments	
	The following amendments must be submitted to PRB for approval before implementation- • Any substantial amendment to a CTIMP (except category C amendments, or category B amendments which have no impact on ICRF) • Any other amendment which has a significant operational impact on the ICRF
	Send all amendments (including those which do not fall into the categories above) to the study contact to ensure all ICRF documentation remains up-to-date at all times. Refer to *ICRF-OR10* for further details.
	Submit amendment details to ICRF GM prior to or at the same time as Ethics/HRA/regulatory submission where possible (as applicable).
	Submit the completed CTIMP amendment checklist (*ICRF-OR10 Fm1*) to ICRF GM for reference once the amendment has full approval(s). If there is any change to the risk assessment, please indicate this on the amendment checklist (*ICRF-OR10 Fm1*) and submit a revised CRAMP to include these changes before the amendment is implemented.
	Send a completed Change Form to the GM highlighting the changes for any non-CTIMP SAs that have a significant impact on the ICRF

End of study	
	Submit the completed end of study notification form (see ICRF-OR09 Form 9) to ICRF GM (or delegate), once your study has ended in ICRF.

	Inform ICRF of all publications that relate to work facilitated by the ICRF and acknowledge the CRF in any publications using the current wording on the website
	Refer to the End of Study Procedures SOP (ICRF-OR28) and use the checklist to ensure that all study closure activities are completed.

7. Related Documents and References

ICRF Documents

- ICRF-POL02 Operational Policy
- ICRF-OR05 Induction SOP
- ICRF-OR34 Internal PRB Review

Relevant Forms

- ICRF-OR09 Form 1 ICRF Application Form
- ICRF-OR09 Form 3 Clinical Risk Assessment and Management Plan (including guidance notes)
- ICRF-OR09 Form 5 PRB Change Form
- ICRF-OR09 Form 6 Booking request single visit
- ICRF-OR09 Form 7 Booking request multiple visits
- ICRF-OR09 Form 9 End of Study Notification Form
- ICRF-OR10 Form 1 Amendment checklist & Training Log
- ICRF-OR09 Form 11 PRB Renewal Request Form

Appendix 1: PRB Approval Process Flowchart