

Clinical Pathway / Standard Operating Procedure Details: Clinical	
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Approved by	Deputy Medical Director
Superseded documents	
Relevant regulations/legislation/guidelines	RECOVERY Randomised Evaluation of COVID-19 Therapy (RECOVERY) Consent Form RECOVERY Trial Integrated Research Application System

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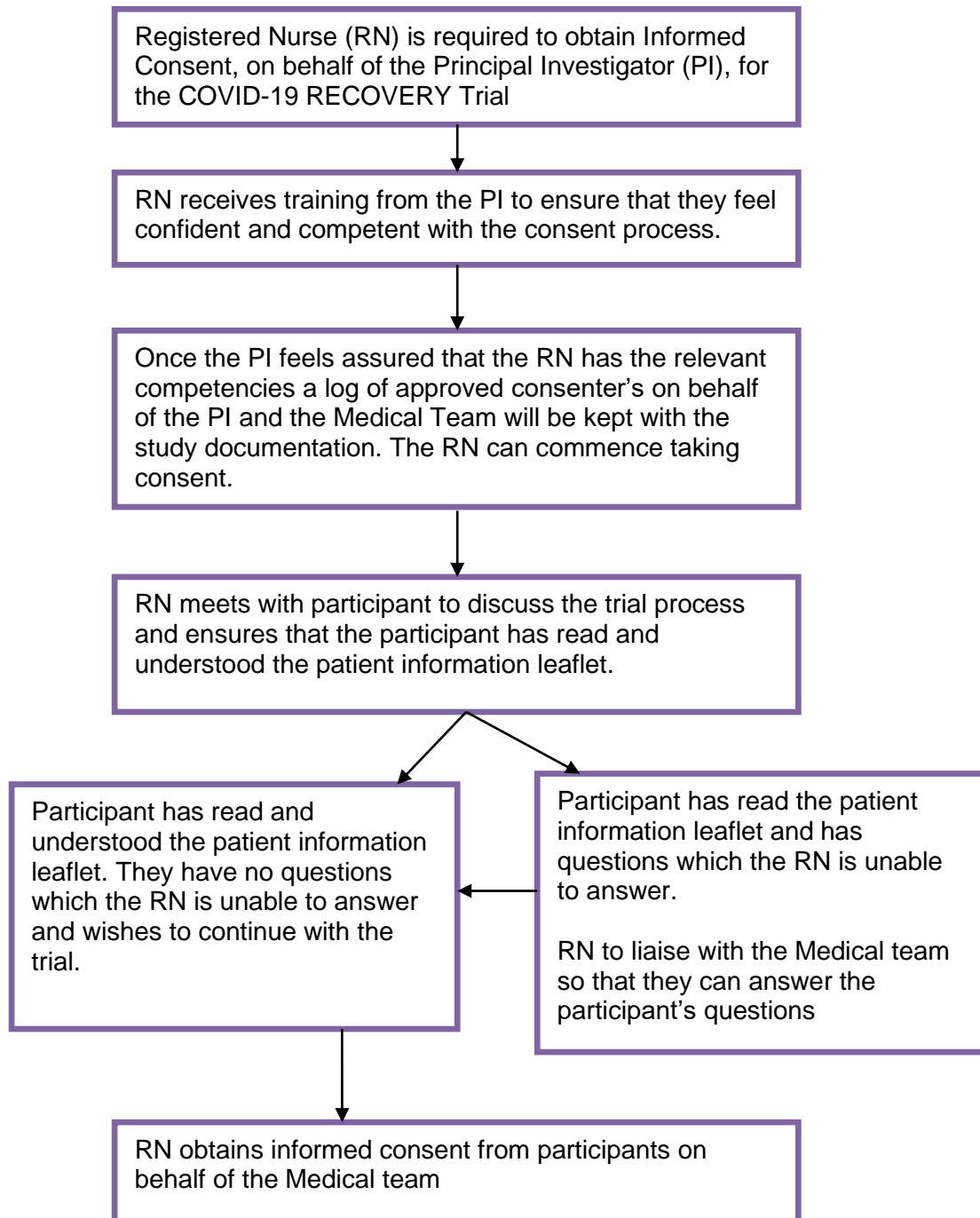
Please be advised that the Trust discourages the retention of hard copies of policies and procedures and can only guarantee that the policy on the Trust Intranet is the most up to date version

Version Control			
Date	Version Number	Change Details	Approved by

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Procedure Pathway



1. INTRODUCTION / PURPOSE

This SOP aims to define the process for Registered Nurses obtaining informed consent from patients / staff who wish to participate in the COVID RECOVERY Trial.

It is the policy of MCHFT that no one will be discriminated against on grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. The Trust will provide interpretation services or documentation in other mediums as requested and necessary to ensure natural justice and equality of access.

2. SCOPE

This SOP applies to Research Nurses and other Registered Nurses within MCHFT.

3. PROCEDURE

Details of the process are in the format of a pathway, and inserted on page 3 of this document.

Responsibilities of taking consent

The Principal Investigator (PI) is responsible for the process of patient consent in a research study. Often the actual consent taking process is delegated to a number of individuals whom the PI is satisfied have received appropriate training in the taking of consent for a particular trial. The RECOVERY trial is a clinical trial into an investigational medicinal product and as such the delegation of consent taking to a research nurse requires special consideration.

The RECOVERY trial has ethical approval by The East of England Research Ethics Committee. The application for such approval contains a clear expectation that the taking of consent will be performed by either medical staff or research nurses. The RECOVERY trial protocol and guidance from the trial site all contain provision for the consent taking process to be delegated to a research nurse.

Assurance of staff competence in the consent process

All Registered Nurses taking informed consent for the purpose of the RECOVERY trial must complete the trial specific on-line training and be fully familiar with the trial protocol. Once this is completed the Registered Nurse will receive an email confirmation from the trial centre confirming that they have completed the trial specific training.

A copy of this email confirmation must be sent to the local Principal Investigator. The Registered Nurse must then sign and date the delegation log indicating clearly which duties they will be undertaking on the RECOVERY trial. The Principal Investigator must then sign and date the delegation log to indicate they are happy for the individual Registered Nurse to perform the delegated duties.

4. DEFINITIONS

(When appropriate, a list of definitions should be included for terms used in the SOP. Acronyms and abbreviations should be explained at the point of use within the SOP and not listed in this section).

4.1 **Standard Operating Procedure (SOP)**

A SOP is a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of a process in an individual setting.

5. **RESPONSIBILITIES / DUTIES**

Principal Investigator – is the Lead for the trial within MCHFT. He /she will ensure that they train the Registered Nurses to obtain informed consent on their behalf.

Registered Nurse – To take informed consent from the trial participant once training has been completed and deemed competent by the Principal Investigator.

Research Nurses - To take informed consent from the trial participant once training has been completed and deemed competent from the Principal Investigator. To collate a signed log of approved consenters on behalf of the Principal Investigator and the Medical Team and keep it with the trial/study documentation.

6. **ASSOCIATED DOCUMENTS**

RECOVERY Randomised Evaluation of COVID-19 Therapy (RECOVERY) Consent Form
 RECOVERY Trial Integrated Research Application System

7. **Consultation and Communication with Stakeholders**

Deputy Medical Director
 Deputy Director of Nursing and Quality
 Head of Patient Safety and Quality Improvement
 Research Nurses
 Corporate Quality Governance Manager

8. **MONITORING AND REVIEW**

Standard/process/issue required to be monitored	Monitoring and Audit			
	Process for monitoring e.g. audit	Responsible individual /group	Frequency of monitoring	Responsible committee
1. Duties	SOP review		3 years	

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9. INTERNAL AND EXTERNAL REFERENCES

9.1 Internal References

9.2 External References

10 APPROVAL

Approving Committee: Deputy Medical Director

Date of Approval: November 2020

Renewal Date: 31st October 2023

NOTE: Should the SOP be a cross divisional document then approval must be sought from all affected divisions to ensure it is a valid and sufficient document. It is the responsibility of the lead division to ensure that this is completed and evidence of such is obtained.

Equality Impact Assessment

Please read the Guide to Equality Impact Assessment before completing this form.
 The completed assessment is to form part of the policy/proposal/business case appendices when submitted to governance-policies@mcht.nhs.uk for consideration and approval.

POLICY/DOCUMENT/SERVICE.....

SECTION A

A	Does the document, proposal or service affect one group less or more favourably than another on the basis of:	Yes/No	Justification & data sources. Include nature of impact. Also record provisions already in place to mitigate impact.
1	Race, ethnic origins or nationality	No	
2	Sex	No	
3	Transgender	No	
4	Pregnancy or maternity	No	
5	Marriage or civil partnership	No	
6	Sexual orientation including lesbian, gay and bisexual people	No	
7	Religion or belief	No	
8	Age	No	
9	Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
10	Economic/social background	No	
B	Human Rights – are there any issues which may affect human rights		
1	Right to Life	No	
2	Freedom from Degrading Treatment	No	
3	Right to Privacy or Family Life	No	
4	Other Human Rights (see guidance note)	No	

Where an impact has been identified in Section A, please outline the actions that have been agreed to reduce or eliminate risks in Section B.

If there are no impacts identified in Section A, completion of Section B is not necessary.

SECTION B

Please expand tables below as necessary

SECTION B NUMBER A1-10, B1-4	NATURE OF IMPACT	EVIDENCE	STAKEHOLDER INVOLVEMENT	ACTION	COST	LEAD	TIMESCALE	RISK SCORE