TRIAL FORGE

Overview of COVID-19 trials – consent process and materials

Trial acronym and title	Email/link	Summary/interventions	Setting	Population	Available Participant Information Leaflet (PIL)	Available Consent Forms	Ethical approval and registration details
REMAP-CAP/ REMAP-COVID A Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia	ukremap-cap@icnarc.org https://www.remapcap.org/	This study will use a study design known as a REMAP, a Randomised, Embedded, Multifactorial, Adaptive Platform trial. The primary objective of this REMAP is, for adult patients with severe community-acquired pneumonia (CAP) who are admitted to an ICU, to identify the effect of a range of interventions to improve outcome as defined by the occurrence of death during the index hospital admission censored 90 days from the date of enrolment. The primary outcome in the pandemic domain is days alive and without intensive care at 21 days from enrolment.	Secondary care /hospital CTIMP	adult patients with severe community-acquired pneumonia (CAP)	[note PIL and consent forms are in one PDF file] Irish version study information and deferred assent form for relatives/Next-of-kin to assent on behalf of patient COVID-REMAP-CAP_DUB-VUH_Deferred Assent form V3.0 18/04/2020 Irish version study information and consent for study participant once regained capacity to consent COVID-ConsentREMAP-CAP_SVUH-_V3.0 _18.04.2020_	[note PIL and consent forms are in one PDF file] Irish study version of assent by relative/next-of-kin Irish study version of consent by study participant once regained capacity to consent Documentation includes withdrawal of previously given consent for all or parts of study interventions by relative/next-of-kin and participant	Ethics in UK - REC reference 18/LO/0660 Ethical approval in [from website map 02.06.2020] Australia Belgium Croatia Germany France Hungary Ireland Netherlands New Zealand Portugal Romania Spain United Kingdom USA Saudi Arabia EudraCT Number: 2015-002340-14 **Used Irish Department of Health guidance and templates**

Summary prepared by Hanne Bruhn, University of Aberdeen

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RECOVERY RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)	recoverytrial@ndph.ox.ac.uk https://www.recoverytrial.net Note – linked with PRINCIPLE https://www.phctrials.ox.ac.uk/principle-trial/ (EudraCT number: 2020-001209-22)	The Randomised Evaluation of COVID Therapy (RECOVERY) trial will test if existing or new drugs can help patients hospitalised with confirmed COVID-19. The first two therapies to be tested will be iopinavir-ritonavir (an HIV drug) and low-dose corticosteroids, which will be evaluated to see if they are safe and effective when added to the usual standard of care. The trial will have an 'adaptive' design, meaning it can test new therapies as they become available. The team's aim is to have data available to inform patient treatment within three months.	Secondary care/ hospital CTIMP	Adults with COVID-19 admitted to hospital	[note PIL and consent forms are in one PDF file] RECOVERY trial ICF/PIL V3.007-Apr-2020 RECOVERY Legal representative PIS– V1.108-Apr-2020 Translations of recovery participant information sheet+ consent form: Arabic Bengali Chinese Farsi French Portuguese Punjabi Spanish Urdu	Capacity and emergency consent: Participant consent (capacity) Participant consent (capacity) but unable to sign/witnessed consent Legal representative consent (no capacity) Translations of recovery participant information sheet+ consent form: Arabic Bengali Chinese Farsi French Portuguese Punjabi Spanish Urdu	UK wide REC Ref 20/EE/0101 EudraCT 2020-001113-21 **Used WHO guidance and templates**
PRINCIPLE Platform randomised trial of interventions against COVID-19 in older people [PRINCIPLE and RECOVERY collaborate]	principle@phc.ox.ac.uk https://www.phctrials.ox.ac.uk/principle-trial/	We aim to find out whether selected treatments given to those at higher risk of becoming more ill when they are infected with COVID-19 can help reduce the need for hospitalisation and the length of stay required, helping people recover quicker and with fewer complications. All people included in the study will be provided with a test for COVID-19. Some will receive the medication we are testing and	Primary care/ General practice (family doctor) CTIMP	Anybody aged 50 to 64 years with: Weakened immune system (e.g. taking chemotherapy) Heart disease Lung disease Diabetes not treated with insulin	Pictorial participant information leaflet for people with communication problems/aphasia PRINCIPLE Pictorial Participant Information Sheet v1.0 20.04.2020 Participant information leaflet for participants	Informed consent is collected **online**: PRINCIPLE Consent Form V1.0 27.3.2020	Wales and England REC Ref 20/SC/0158 EudraCT number: 2020-001209-22 **Used HRA guidance and templates**

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		some will be allocated to current usual care without the medication we are testing.		▯ Liver disease ▯ Stroke or neurological problem With a new cough and/or fever. People aged 65 or over even without other illnesses who have symptoms of COVID-19 are also eligible to take part.	without communication problems PRINCIPLE PIS_v2.1 21.04.20_Clean.pdf		
RECOVERY-RS RECOVERY-RS Respiratory Support : Respiratory Strategies in COVID-19; CPAP, High-flow, and standard care	RECOVERY-RS@warwick.ac.uk https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/	The RECOVERY-RS trial will compare the effectiveness of three ventilation methods; Continuous positive airway pressure (CPAP): this treatment applies mild to high air pressure on a continuous basis through a tightly fitted face mask. It keeps the airways continuously open in people who are able to breathe normally on their own, but need help keeping their airway clear. High flow nasal oxygen (HFNO): this is a way of giving humidified (moistened) and warmed oxygen through tubes into the nose. The oxygen is delivered very quickly to help patients who have low oxygen levels and find breathing on their own difficult. Standard care: standard treatment will involve oxygen delivered via a normal face mask or tubes in the nose.	Secondary care/Hospital Non-CTIMP	Adult, critically ill patients, with suspected or confirmed, COVID-19	Short Participant information leaflet [for participants themselves once they are better] - recovery_rs_short_patient_information_sheet_v2_03-04-20 More detailed Participant information leaflet [for participants themselves once they are better] recovery_rs_patient_information_sheet_v2_03-04-20 Assent Information Sheet (Northern Ireland) [for friends or relatives to give assent] - recovery_rs_assent_form_v2_03-04-20	Using the emergency research consent process: Consultee declaration form [to be completed by friends or family in Wales, Northern Ireland and England] - recovery_rs_consent_form_consultee_v1_01-04-20_for_upload_8-4 Deferred consent form [to be completed by the participant once they are better] - recovery_rs_consent_form_deferred_consent_v1_01-04-20	UK - Wales Northern Ireland England REC reference 20/HRA/1696 ISRCTN16912075 **Used HRA guidance and templates** **Most up to date versions of consent materials is available here: https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/patients/**

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REALIST Repair of Acute Respiratory Distress Syndrome by Stromal Cell Administration (REALIST)	[No email currently available] Study summary only: http://www.nictu.hscni.net/realist/	Repair of Acute Respiratory Distress Syndrome by Stromal Cell Administration (REALIST) trial: An open label dose escalation phase 1 trial followed by a randomised, double-blind, placebo-controlled phase 2 trial. The primary objective is to assess the safety of a single intravenous infusion of MSCs in patients with ARDS due to COVID-19	Secondary care/Hospital CTIMP	Adults with Acute Respiratory Distress Syndrome (ARDS) due to covid19.	[note covering statement, PIL and consent forms are in one PDF file] Covering statement, information leaflet and consent form for Professional Legal Representative (Pro LR) [the treating clinician on behalf of the patient – information sheet and consent form] 20200107_REALIST_ProLR PISICF_Final v3.0.pdf Covering statement, information leaflet and consent form for Personal Legal Representative (Per LR) [relative/friend/partner – information sheet and consent form] 20200107__REALIST_PerLR PISICF_Final v3.0.pdf Covering statement, patient information leaflet and consent to continue form [information and consent for the patient when they regain capacity] 20200107 REALIST_Cons to Cont PISICF_Final v3.0.pdf	Using the emergency research consent process: Personal legal representative telephone agreement form [when the friend/relative/partner is not available at the hospital to sign consent in person, it can be collected over the phone with witness] Telephone PerLR agreement form v1.0_23.03.2020_Final Asking treating clinician to consent on behalf of the patient until they regain capacity Asking Friend/relative/partner to consent on behalf of the patient until they regain capacity Consent from patient to continue on study when they regain capacity	UK - Northern Ireland, England and Wales REC reference 18//NE/0006 EudraCT number: 2017-000584-3 **Used HRA guidance and templates**

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COV001: A study to assess a new COVID-19 vaccine in healthy adults A phase I/II study to determine efficacy, safety and immunogenicity of the candidate COVID-19 vaccine ChAdOx1 nCoV-19 in UK healthy adult volunteers	[no email available] https://covid19vaccinetrial.co.uk/home	This study will enable us to assess if healthy people can be protected from COVID-19 with this new vaccine called ChAdOx1 nCoV-19. It will also give us valuable information on safety aspects of the vaccine and its ability to generate good immune responses against the virus. (CTIMP)	Community/ healthy volunteers	Healthy adults aged between 18 and 55 years.	Participant information leaflet COV001 PIS version 5.0, 21st April 2020. PDF	[not available]	England and Wales REC Ref: 20/SC/0145 EudraCT 2020-001072-15 **Used HRA guidance and templates**