THE PSYCHOLOGICAL IMPACT OF SURVIVING AN INTENSIVE CARE ADMISSION DUE TO CORONAVIRUS DISEASE 2019 (COVID-19) ON PATIENTS IN THE UNITED KINGDOM

SHORT STUDY TITLE / ACRONYM

Psychological **Im**pact of **COVID**-19 on Intensive Care Survivors / PIM-COVID

PROTOCOL VERSION NUMBER & DATE

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Liverpool University Hospitals NHS Foundation Trust

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The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: ..... Date: ..... /..... /.....

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Position: Research Governance Manager

Chief Investigators:

Date: ..... /..... /.....

Signature: ……..

Name: Alicia A C Waite

Signature: …….. Date: ..... /..... /.....

Name: Ingeborg D Welters

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List of Abbreviations

ARDS	Acute Respiratory Distress Syndrome
APACHE II	Acute Physiologic Assessment and Chronic Health Evaluation II
ASR	Annual Safety Report
CA	Competent Authority
CAS-1R	Cognitive Attentional Syndrome Scale-1 (Revised)
CI	Chief Investigator
COVID-19	Coronavirus Disease 2019
CRF	Case Report Form
HADS	Hospital Anxiety and Depression Scale
HRQoL	Health-Related Quality of Life
ICU	Intensive Care Unit
ICM	Intensive Care Medicine
IES-6	Impact of Event Scale-6
IES-R	Impact of Events Scale-Revised
Main REC	Main Research Ethics Committee
NHS	National Health Service
NIHR	National Institute for Health Research
PI	Principle Investigator
PICS	Post-Intensive Care Syndrome
PTSD	Post Traumatic Stress Disorder
R&D	Research & Development
RD&I	Research, Development and Innovation
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SOFA	Sequential Organ Failure Assessment
SOP	Standard Operating Procedure
TRIC	Trainee Research in Intensive Care

1. Study Summary

Title	The psychological impact of surviving an intensive care admission due to coronavirus disease 2019 (COVID-19) on patients in the United Kingdom
Protocol short title / Acronym	**P**sychological **Im**pact of **COVID**-19 on Intensive Care Survivors / PIM-COVID
Protocol Version number and Date	Version: 1.3 15 March 2021
IRAS	282400
Is the study a Pilot?	No
Study Duration	24 months
Methodology / Study Design	Multicentre longitudinal study
Sponsor	Liverpool University Hospitals NHS Foundation Trust
Co-Chief Investigators	Dr Alicia Waite Professor Ingeborg Welters
Medical conditions under investigation	1) Anxiety, 2) depression and 3) trauma symptoms
Purpose of study	To assess the short- and long-term psychological impact on patients who have survived an admission to intensive care due to COVID-19, and identify possible predictors of anxiety, depression and trauma symptoms in this patient group.
Primary objective	To identify the proportion of patients surviving an admission to intensive care due to COVID-19 who experience anxiety, depression and/or trauma symptoms in the 6 months post-discharge, assessed using the Hospital Anxiety and Depression Scale (HADS) and the Impact of Event Scale-6 (IES-6), respectively.
Secondary objectives	1. Identify demographic, clinical, physical and/or psychosocial predictors of depression, anxiety and/or trauma symptoms at 3-, 6- and 12-months post discharge from ICU. 2. Assess the feasibility of using a self-reported online questionnaire to assess anxiety, depression and/or trauma symptoms in patients following ICU admission.

Main Inclusion and Exclusion Criteria	**Inclusion criteria:** 1. Adult patients ≥18 years 2. Survived to intensive care / high dependency unit discharge following an admission of ≥24 hours 3. Diagnosed positive for COVID-19 **Exclusion criteria:** 1. Unable to complete questionnaires 2. Unable or unwilling to consent 3. Unable to speak, understand or communicate in English 4. Patients with diagnosed pre-existing cognitive impairment (at the time of ICU admission) 5. Patients with no fixed abode, at which postal questionnaire might be not received, and who have no access to a personal email address.
Randomisation	Not applicable
Statistical Methodology and Analysis	Trajectories of anxiety, depression, and trauma symptoms will be estimated using growth curve analysis. We will estimate and predict individual survivors' slope and intercept scores. We will then regress predictor variables onto intercept and slope scores for all outcomes to identify variables likely to determine trajectories of anxiety, depression and trauma symptoms. Feasibility will be assessed using descriptive analyses.

2. Introduction

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was first reported in Wuhan, China in December 2019 (1). SARS-CoV-2 was later termed coronavirus disease 2019 (COVID-19) by the World Health Organisation (WHO). On March 12, 2020 a pandemic was declared, which continues to emerge globally (2). At the time of writing, COVID-19 infections number over one million and have been responsible for over 123,000 deaths worldwide (3).

COVID-19 is responsible for a spectrum of clinical presentations, ranging from asymptomatic or mild disease in the majority of patients, to pneumonia and acute respiratory distress syndrome (ARDS) in those more severely affected (1). Initial reports suggested 5% of 1099 patients in China with confirmed COVID-19 were admitted to an intensive care unit (ICU) (4). Meanwhile, 12% of positive cases required ICU admission in Lombardy, Italy, accounting for 16% of all hospitalised patients (5). Based on recent UK-wide data from 258 ICUs where at least one patient has had COVID-19, the ICU mortality rate amongst patients with confirmed COVID-19 is 41.1% (6).

In a 5 year longitudinal study of patients who developed ARDS not caused by COVID-19, prolonged symptoms of anxiety, depression and post-traumatic stress disorder (PTSD) were found to affect 23-38% of patients, with a median duration of symptoms of between 33 and 39 months (7). Not all patients admitted to ICU with COVID-19 will have ARDS, but admission to ICU is itself associated with a significant burden of post-ICU psychological sequelae. Symptoms of anxiety, depression and PTSD have been reported to affect up to 73% of survivors (8-10). Furthermore, symptoms of anxiety, depression and PTSD persist in 34% (8), 29% (9) and 34% (10) of ICU survivors respectively at 12-14 months following ICU admission.

The severe acute respiratory syndrome (SARS) pandemic in 2002-2003 was also caused by a coronavirus, but affected significantly fewer individuals despite having a higher case fatality rate (10.9% (11) vs 3.2% (4)). At the peak of the SARS outbreak, patients reported significantly higher stress levels than healthy controls (12), with similar symptoms reported up to 1 year later, with 64% of patients reporting symptoms suggesting psychiatric morbidity (13). Furthermore, amongst SARS survivors, females were more likely to have symptoms of anxiety, depression, stress and trauma, and were three times more likely than males to have psychiatric morbidity (13). Female gender was also found to be an independent risk factor for chronic PTSD up to 30 months after the SARS outbreak (14). These results contrast with pre-existing data for ICU survivors, in whom gender is not a significant risk factor for anxiety, depression or PTSD (8-10). Instead, recognised risk factors for emotional distress following ICU

admission include previous psychiatric morbidity, receipt of benzodiazepines in ICU and psychiatric symptoms during admission (8-10). Furthermore, psychological symptoms may be part of Post Intensive Care Syndrome, which also includes cognitive and physical impairments that are new or have worsened following ICU admission and persist on discharge from hospital (15, 16).

Whilst data emerges about the short-term impact of COVID-19 (17), the long-term implications to patients and healthcare systems remain unclear. With population-wide social distancing and societal lockdown enacted in many countries, the mental health of the general public is under strain(18). Data from previous pandemics suggests that pandemic-related factors such as quarantine may also have an impact on the psychological wellbeing of ICU survivors (19). It is plausible that this heightened anxiety primes patients, who subsequently require treatment in ICU for COVID-19, to develop psychological distress (17).

We anticipate that there will be a significant burden to healthcare systems as a result of psychological distress. Current national guidelines state that at-risk ICU survivors who have had an admission of more than 4 days should be invited to a follow up clinic 2-3 months after discharge from ICU (20). However, hospital and community based services to support ICU survivors in their recovery were limited before COVID-19, with some hospitals not even offering an ICU follow up clinic (21). The number of patients expected to require admission to ICU during COVID-19 is far beyond existing UK critical care capacity, and in the context of enhanced baseline societal anxiety, the potential volume of patients with post-ICU psychological distress could far exceed existing healthcare capacity overwhelming current services. In order to be able to expand services as necessary and support ICU survivors properly to help them regain their quality of life, and return to working and contributing to society, we must first identify how many, and to what extent patients are affected.

In this study, we aim to: 1. identify the proportion of COVID-19-positive critical care survivors who experience anxiety, depression and/or trauma symptoms up to 12 months after discharge from ICU, using validated tools; and 2. identify predictors of post-ICU anxiety, depression and/or trauma in COVID-19 ICU survivors. This information may be used to inform healthcare systems about the psychological support required for survivors of this pandemic, and may inform healthcare planning for future pandemics.

3. Study Objectives, Design and Statistics

3.1 Study Aim

To assess the short- and long-term psychological impact on patients who have survived an admission to intensive care due to COVID-19 in the United Kingdom, and identify possible predictors of anxiety, depression and trauma symptoms in this patient group.

3.2 Study Objectives

Primary objective:

To identify the proportion of patients who survive ICU admission following treatment for COVID-19 that experience anxiety, depression and/or trauma symptoms at 6 months, assessed using the Hospital Anxiety and Depression Scale (HADS) and the Impact of Event Scale-6 (IES-6), respectively.

Exploratory objectives:

1. Identify demographic, clinical, physical and/or psychosocial predictors of depression, anxiety and/or trauma symptoms at 3-, 6- and 12-months after ICU discharge in patients being treated for COVID-19 within the ICU.
2. Assess the feasibility of using a self-reported questionnaire to assess anxiety, depression and/or trauma symptoms in patients following ICU admission with COVID-19.

3.3 Study Outcomes

Primary outcome:

Prevalence and incidence of:

1. Anxiety
2. Depression
3. Trauma

Anxiety and depression will be assessed using the HADS. The HADS is a 14-item self-report measure in which participants rate the presence of symptoms of anxiety (7 items) and depression (7 items) over the preceding week using a 4-point Likert scale, with options from 0 (absence) to 3 (extreme presence). Responses are summed to produce two subscale scores, ranging from 0-21, with higher scores indicative of higher anxiety and depression levels, respectively. The HADS is widely used to assess anxiety and depression in people with physical health difficulties, and demonstrates good psychometric properties when used in an intensive care setting. Cut-off scores of ≥8 on anxiety and depression subscales of the HADS were used to define caseness (22, 23). A recent meta-analysis (24) showed the anxiety cut-off to

predict structured interview diagnoses of either anxiety or depression with a sensitivity of 73% and specificity of 65%, and the depression cut-off to predict diagnosed depression with a sensitivity of 86% and specificity of 81%.

Trauma will be assessed using the IES-6. The IES-6 is a validated tool in survivors of ARDS for screening for post-traumatic stress disorder. It is an abbreviated version of the IES-R test, and contains six questions (25). We have chosen the IES-6 over the IES-R because it is shorter, is validated in a very similar patient population, will provide similar information, and is likely to have a higher completion rate by patients because it is shorter. Furthermore, in collaboration with ICU steps it was felt that this was the best approach for this cohort of ICU survivors.

Exploratory outcomes*:*

1. Identify demographic, clinical, physical and/or psychosocial predictors of depression, anxiety and/or trauma symptoms at 3-, 6- and 12-months post discharge from ICU.

    a. Demographic and clinical predictors.

(*See* Schedule of Study Procedure *for specific data that will be collected.*)

    b. Physical predictors.

The EuroQol 5-dimension, 5-level questionnaire (EQ-5D-5L) is a five-domain, self-report measure assessing mobility, self-care, usual activities, pain/discomfort and anxiety/ depression. Participants are asked to rate each domain, indicating no problems, slight problems, moderate problems, severe problems or extreme problems. In addition, participants are invited to rate their health on a visual analogue scale from 0-100, where zero represent the worst health imaginable and 100 represents the best health imaginable. EQ-5D-5L has been recommended for use in all studies assessing the HRQoL of critically ill patients (26). In this study, EQ-5D-5L will be used as a subjective assessment of the physical function of participants.

    c. Psychosocial predictors (metacognitive beliefs and processes).

Metacognitive beliefs and processes will be assessed using the Cognitive Attentional Syndrome Scale-1 (Revised; CAS-1R (27)). The CAS-1R is a 10-item self-report measure assessing positive and negative metacognitive beliefs, frequency of worry/rumination and the use of a range of counterproductive coping strategies used in response to negative thoughts and feelings. Participants are asked to rate the degree

to which they have engaged in a particular coping strategy or thought process during the previous week. Responses are scaled from 0%-100% and are summed to produce a total score. Higher scores indicate greater conviction in metacognitive beliefs and greater use of maladaptive coping strategies to manage distress. The CAS-1R has demonstrated good psychometric properties in physical health populations.

2. Assess the feasibility of using a self-reported online questionnaire to assess anxiety, depression and/or trauma symptoms in patients following ICU admission.

Outcomes:

- Recruitment number (total number of patients recruited per month)
- Recruitment rate (proportion of those deemed eligible recruited)
- Retention rate (proportion of participants who provide data at subsequent data capture points)
- Rate of missing key data
- Estimation of quantities needed for an accurate sample size calculation (e.g. HADS standard deviation)

3.4 Study Design

This is a multicentre longitudinal study.

3.5 Study Statistics

This study is planned as a descriptive study in an effort to quantify the psychological impact on ICU survivors of COVID-19. It is anticipated that the study will report its findings using descriptive methods in the absence of a comparator group.

Trajectories of anxiety, depression, and trauma symptoms will be estimated using growth curve analysis. To improve power, we will use the full range of anxiety, depression and trauma symptom scores (not cut-off scores). Growth modelling is latent variable covariance modelling to estimate the intercept (value of the initial observation) and slope (the rate of change from this observation over time) of a time series of mean scores. We will estimate full sample single class models (eg, assuming homogeneity across the sample) for each outcome. Initial fixed parameters will be; error variance constrained to equality across observations, mean intercept and slope constrained to zero, intercept and slope constrained to equality, and intercept and slope covariance constrained to zero. Parameters will be systematically relaxed in that order until good fitting models (CFI > .95, RMSEA .05) are identified with maximum fixed parameters.

Linear and quadratic slope models will be tested; linear models being defined as slope parameters 0, 1, 4, and 12 and quadratic slopes as 0, 1, 8 and 24.

We will estimate and predict individual survivors' slope and intercept scores. Scores will be calculated using the regression method, setting intercepts for observed variables to 0 and imposing equality of variance. We will then regress predictor variables onto intercept and slope scores for all outcomes to identify variables likely to determine trajectories of anxiety, depression and trauma symptoms.

3.6 Sample size

There is no formal sample size required. Overall we aim to recruit 1000 patients. We will initially approach 20 intensive care units for participation. If necessary we will extend the number of recruiting units to facilitate reaching this recruitment target. We have factored in a 40% return rate, so we will have to send out 2500 questionnaires in order to achieve our target.

4. Recruitment and Withdrawal of Participants

4.1 Recruitment

Recruitment will take place at hospitals across the UK, and be conducted by junior doctors who are either training, or have a specialist interest, in intensive care medicine; and/or allied health professionals working in intensive care (including Advanced Critical Care Practitioners). Therefore, recruitment will be balanced within the demands of the clinical workload. It is intended that all patients discharged from a recruiting ICU, that were admitted and treated for COVID-19, will be given an information sheet explaining the study to them and explaining the possibility of receiving three questionnaires during the year following discharge. Where this is not feasible, every reasonable effort will be made to contact these patients prior to hospital discharge. All ICUs with members in the Trainee Research in Intensive Care (TRIC) will be invited to participate.

4.2 Inclusion criteria

1. Adult patients ≥18 years
2. Survival to intensive care / high dependency unit discharge following an admission of ≥24 hours
3. Treated for COVID-19

4.3 Exclusion criteria

1. Unable to complete questionnaires
2. Unable or unwilling to consent
3. Unable to speak, understand or communicate in English
4. Patients with diagnosed, pre-existing cognitive impairment (at the time of ICU admission)
5. Patients without a fixed abode, at which postal questionnaires might be received, and who have no access to a personal email address.

4.4 Criteria for Premature Withdrawal

A patient may request to be withdrawn from the study at any time, for any reason, without prejudice and without an impact on their clinical care. A patient may also be withdrawn from the study at the request of his/her legal representative or clinical team, for any reason.

5. Study Procedures

5.1 Screening Procedures

All patients discharged from the ICU will be screened against inclusion and exclusion criteria prior to enrollment. A screening and enrolment log will be kept with site files and will be archived following the end of the study (see section 7.3).

5.2 Consent, Enrolment and Participant Follow-up Procedures

On ICU discharge, where possible, patients will be provided with an information sheet outlining the study. A member of the research team with a valid GCP certificate will provide verbal information about the study and answer any questions. Patients will be given the option to opt out of the study at this point, and thenceforth. Patients will also be given the option to opt in and be contacted by phone, email and/or post. Even if a patient opts in, and provides their contact details, they can choose to not participate in the study, and when they receive the invitation to participate in the first survey they can actively decline to participate or just not respond to the invitation. If the patient indicates that they do not wish to participate, they will be withdrawn from the study. If they do not indicate that they do not want to be contacted, and do not reply to the first survey, they will still be sent subsequent surveys and invited to participate in those. Critically ill patients often have impaired capacity as a result of their underlying illness and/or sedating medications, but usually regain capacity prior to being discharged home. It is important that only patients with capacity participate in the study. A patient will only be provided with an information leaflet in hospital once they have regained capacity. If a patient has not been given an information leaflet prior to being discharged home, they will be sent an information sheet by post along with an invitation to participate. If after receiving the information sheet and unique login details, the patient has not yet indicated via the REDCap database that they either consent to participating in the study or decline to participate, they will be contacted by telephone by the study team (unless they have previously opted out of being contacted by phone). There are three possible outcomes of this telephone contact: i) the patient consents to participating in the study; ii) the patient asks to be contacted again for re-discussion of consent; iii) the patient declines to participate in the study. There are three methods for patients to provide their consent, via i) an online consent form in the REDCap database; ii) witnessed telephone consent; iii) a written consent form, which the patient can request. Verbal agreement to participate in the study will be obtained

by a member of the study team and will be recorded in the patient notes. Verbal agreement must be witnessed by another member of the site study team or site medical staff. The patient may withdraw consent at any stage. Upon withdrawing their consent, a study participant will be given the option for i) any previously collected data to still be included in the data analysis; or ii) all of their data to be removed from the REDCap database, and as such none of their data to be included in the analysis.

Where patients consent to taking part in the study using the online consent form, they will be asked to enter their name and email address, and whether they are happy to be contacted by email, post and/or phone. If patients decide not to provide an email address or their name, the study team will still be able to identify which patient has responded as the link to that consent form is unique to the patient and the REDCap record identifier can be cross referenced with the screening log. Where patients do not consent to taking part in the study, no personal information will be requested.

Eligible patients, who have not already opted out, will be invited to participate in an online questionnaire at 3, 6 and 12 months following discharge from ICU, or alternatively a paper copy of the questionnaire can be sent to them at the relevant time points or they may choose to answer the questionnaire over the phone with a member of the study team documenting their responses on REDCap. Prior to patient contact, electronic healthcare records will be accessed, and/or contact made with the patient's registered general practitioner, to confirm the patient's survival status. This is intended as a pre-contact check to minimise distress caused to families/relatives by making contact in the event a patient has died following discharge from the ICU.

For patients who have provided their email address, an email will be sent at 3, 6 and 12 months with a unique link to their survey. The link to their survey at each timepoint will expire after 1 month. At the beginning of the questionnaire, the study information will be repeated. Patients will be able to leave the study by contacting their local study team at any point during the study. If patients indicate they would prefer to complete a paper version, they will be provided with a pre-paid envelope to return their completed questionnaire. If patients indicate they would like to complete their questionnaire over the phone, this can be arranged with a study team member.

No patient identifiable information will be entered into REDCap prior to gaining patient consent. Patient information that is analysed will be pseudo-anonymised and each patient will have a unique study identifier assigned for use in REDCap. When the patient consents to be part of the study, their name and email address where provided will be stored in the REDCap database. Only the local study team will

have access to this. The REDCap database will be used for the study duration and closed when all data has been acquired. Patient contact details will be kept during the study period only and will not be stored on the REDCap database without the patient's consent. In the event that the patient dies after having consented to participating in the study, then they will remain in the study and their data will be included in the final analysis.

5.3 Schedule of study procedure

Following screening and enrolment after ICU discharge, the following will be collected:

Patient data from medical records:

1. Age
2. Gender
3. Laboratory diagnosis of COVID-19
4. Physical health co-morbidities
5. Mental health comorbidities
6. Socioeconomic status (deprivation index calculated from postcode)

Patient data from self-reported questionnaire:

1. Highest educational level obtained (first questionnaire only)
2. Prior and current experience of, and treatment for, mental health difficulties
3. Current employment status

ICU-acquired data:

1. ICU date of discharge
2. ICU length of stay *
3. APACHE II score
4. Mechanical ventilation received **
5. Delirium during ICU admission ***
6. Benzodiazepine requirement during ICU admission

* Defined as the length of stay recorded on the ICNARC database
** Defined as invasive mechanical ventilation via an endotracheal tube or tracheostomy using PEEP ≥ 5cmH2O
*** Defined as present if recorded in the medical notes during ICU admission or discharge

Psychological assessment via self-reported questionnaire:

The following three self-report questionnaires will be administered at 3, 6 and 12 months following ICU discharge:

1. HADS
2. IES-6
3. CAS-1R

5.4 Accessing locally held data

Where possible, locally collected data that contributes to the ICNARC database will be used rather than directly accessing patient notes. Accessing this data minimises error and bias in this study. Prior to study commencement, an agreement will be sought to access ICNARC data.

5.5 Missing observations

Every effort will be made to minimise missing baseline and outcome data in this study. Reasonable efforts will be made to obtain complete datasets. Where this is not possible, data will be reported as missing in the presentation of the results. In the event that participants are non-responders to the 3- and 6-month questionnaires, the 12-month questionnaire will still be sent to participants (unless consent has previously been withdrawn). This will be accompanied by a telephone call to confirm the patient's willingness to continue as a study participant.

5.6 End of Study Definition

The study end date is deemed to be the date of the last data capture. Reasonable attempts will be made to contact non-responders. The CI has the right at any time to terminate the study for clinical or administrative reasons. The end of the study will be reported to the Sponsor and REC within the required timeframe if the study is terminated prematurely. Investigators will inform patients of any premature termination of the study. Following the end of the study a summary report of the study will be provided to the REC within the required timeframe.

6. Assessment of Safety

6.1 Safety outcomes

Whilst we do not anticipate any adverse events or safety risks for patients or members of the research team from participation in this study, it is possible that patients engaging with this study may be experiencing psychological distress. With each online or paper questionnaire, information will be provided about ICUsteps, a national support group network who are aware of and support this study.

Participants will also be encouraged to engage with their local ICU follow up clinic if available locally (e.g. at 3 months) or contact their GP if they feel they need additional support.

6.2 Ethics Reporting

Approval from a Research & Ethics Committee (REC) will be sought. The REC will be informed about any changes according to the official National Research Ethics System regulations. Local site investigators will be responsible for ensuring appropriate approvals from local research committees, audit committees or R&D centres are obtained as required to ensure compliance with local policies.

6.3 Data Safety and Monitoring Board

This is a longitudinal study with no change in clinical practice. A data safety and monitoring board will not be established.

6.4 Ethics & Regulatory Approvals

The study will be submitted centrally for consideration by a NRES approved Research Ethics Committee and by the HRA, as well as local RD&I approvals.

7. Data Handling

7.1 Confidentiality

- All local sites will maintain an enrolment and recruitment log, which will include patient hospital identification number, name and contact details and will be held in a locked office at the local site. Only members of the local study team will have access to this list.
- Patient confidentiality will only be breached if a participant discloses information which may indicate harm to themselves or others. We will take every opportunity to discuss any possible breaches of confidentiality with patients before informing any appropriate agencies (e.g. patient's registered general practitioner).
- All enrolled patients will be allocated a unique study number which will be used for referencing data recorded and entered into the REDCap database. This study number will be used as the patient identifier to link to clinical variables.
- To avoid the possibility of identifying patients via their postcode, study members will be looking up the deprivation index using government data specific to England, Northern Ireland, Scotland and Wales. This deprivation index will then be entered into the REDCap database. The patient's postcode will be found in the patient's records and not be recorded in the REDCap database.

- All online questionnaires, and online generated data, will be held in a secure server. If necessary, paper copies of questionnaire results will be printed and stored at local sites. Printed questionnaires will be entered into the REDCap database by local study team members, so as to merge all data together for analysis.
- All paper documents (including participants' written consent forms and returned paper questionnaires) will be held securely at the study site in a restricted access area, in line with data protection regulations.
- The Chief Investigator will act as 'Custodian' for all data collected.
- No patient identifiable details will be included in the published study reports.
- No information regarding the study will be released to or by a third party without the prior written consent of the sponsoring institution.
- Representatives of the sponsoring institute may inspect all documents and records required to be maintained by the investigators.

7.2 Case Report Form

Data will be recorded via individual electronic case report forms (eCRF) through the REDCap (https://www.project-redcap.org/) online database tool. Local investigators will be responsible for individual hospital data input into REDCap. Local investigators are responsible for data collection, input and accuracy.

7.3 Record Retention and Archiving

All research and relevant documents will be stored confidentially and securely for 10 years following the end of the study as per the Sponsor's standard operating procedure on research archiving. The members of the study management team will have access to stored data. Upon request, investigators can get access to data from their own site.

7.4 Compliance

The study will be conducted in compliance with the principles of the Declaration of Helsinki (1996), and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework, Trust and Research Office policies and procedures and any subsequent amendments. Personal patient data will be pseudo-anonymised and will be held in compliance with EU General Data Protection Regulations (GDPR) and the UK Data Protection Act (2018).

7.5 Clinical Governance

The study may be selected for audit by any method listed below:

- The project may be identified via the risk assessment process.
- An individual investigator or department may request an audit.
- A project may be identified via an allegation of research misconduct or fraud or a suspected breach of regulations.
- Projects may be selected at random. The Department of Health states that Trusts should be auditing a minimum of 10% of all research projects.
- Projects may be randomly selected for audit by an external organisation.
- Internal audits will be conducted by a sponsor's representative

7.6 Non-Compliance

Non-compliances may be captured from a variety of different sources including eCRFs, communications and updates. The sponsor will maintain a log of the non-compliances to ascertain if there are any trends developing which require to be escalated. The sponsor will assess the non-compliances and action a timeframe in which they need to be dealt with. Each action will be given a different timeframe dependent on the severity. If the actions are not dealt with accordingly, the R&D team will agree to an appropriate action, including an on-site audit. All protocol and GCP deviations will be reported to the Sponsor and serious non-compliance will be reported to REC, in line with the SAE/protocol deviation SOPs of the Sponsor.

7.7 Protocol Amendments

Any changes in research activity will be reviewed and approved by the Chief Investigator and submitted in writing to the appropriate REC and local research site for approval prior to being included in an amended protocol.

7.8 Study Management

The Co-Chief Investigators, Dr Alicia Waite and Professor Ingeborg Welters, will have managerial oversight of the project. The day-to-day management and data collection will be coordinated by the TRIC network, with junior doctors at each site performing patient identification, data collection and appropriate participant contact, in conjunction with allied health professionals working with the TRIC network. The analysis will be led by Dr Steve Brown, with clinical input provided by the TRIC network.

8. Finance and Publication Policy

8.1 Finance

Funding is provided by the Intensive Care Society and the Mersey School of Anaesthesia.

8.2 Publication Policy

It is planned to publish the study results, in mutual agreement with the investigator team, in a scientific journal and present the findings at international congresses. Publication of the results of the study as a whole is intended. Requirements for authorship will follow American Medical Association (AMA) guidance. Any publication will take account of the International Committee of Medical Journal Editors (ICMJE) relevant policies and guidelines. The study will also be registered in a public register in accordance with the recommendations of the ICMJE. Any published data will observe data protection legislation covering the study subject and investigators. Individual findings at individual study sites are known only to the responsible institution. A lay summary of the results will be made available to participants upon their request.

Publications or lectures presenting findings of the study (either as a whole or at individual investigation sites) must be approved by the chief investigator in advance, and the responsible institution reserves the right to review and comment on such documentation before publication. Publication should include details of the sponsor and other major study contributors, but with no patient identifiable details.

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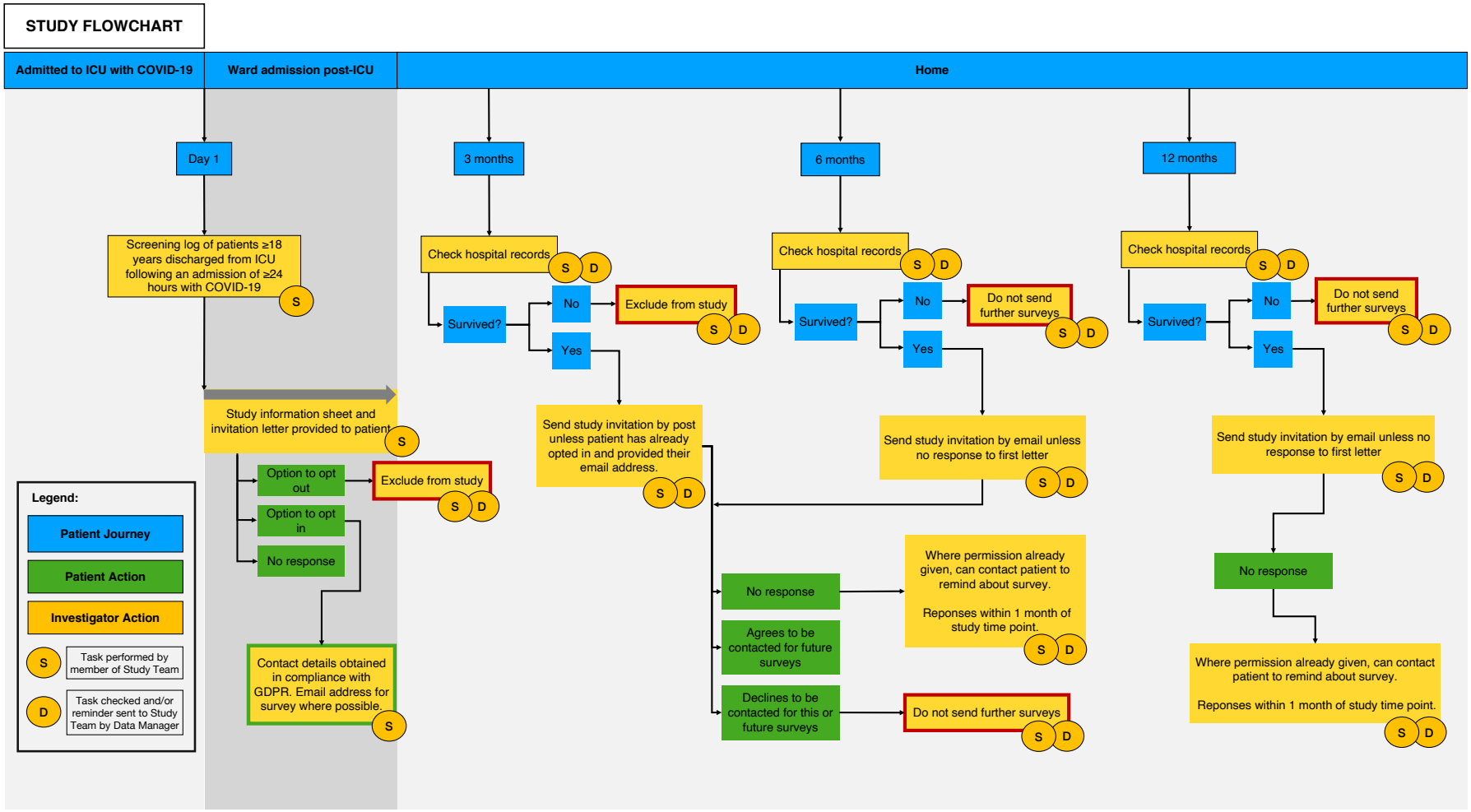
10. Appendices

Appendix 1: Information with regards to Safety Reporting in Non-CTIMP Research

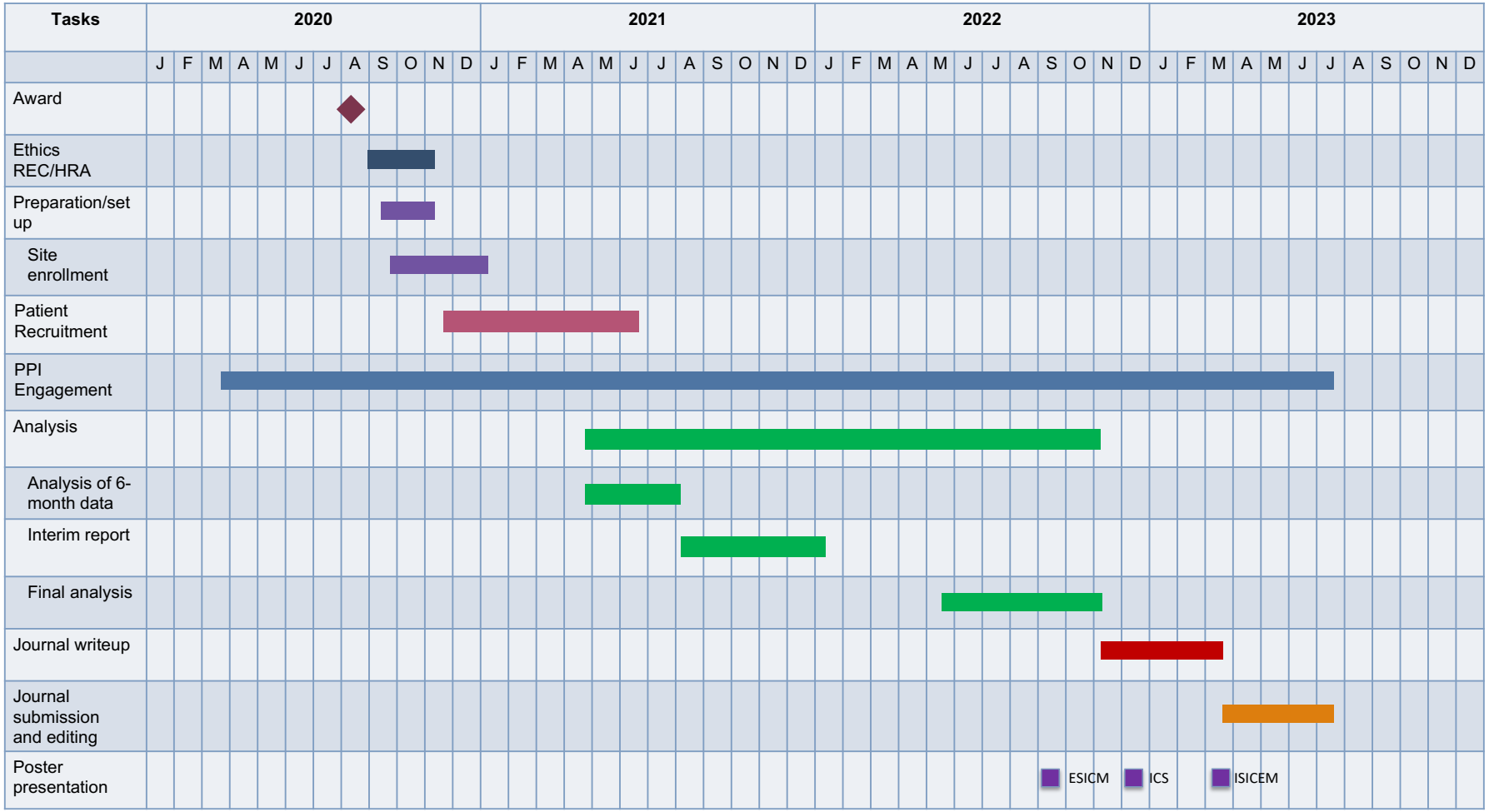
	Who	When	How	To Whom
SAE	Chief Investigator	Report to sponsor within 24 hours of learning of the event Report to the MREC within 15 days of learning of the event	SAE report form for non-CTIMPs, available from NRES website.	Sponsor and MREC
Urgent Safety Measures	Chief Investigator	Contact the sponsor and MREC immediately Within 3 days	By phone Substantial amendment form giving notice in writing setting out the reasons for the urgent safety measures and the plan for future action.	Main REC and sponsor Main REC with a copy also sent to the sponsor. The MREC will acknowledge this within 30 days of receipt.
Progress Reports	Chief Investigator	Annually (starting 12 months after the date of favourable opinion)	Annual progress report form (non-CTIMPs) available from the NRES website	Main REC
Declaration of the conclusion or early termination of the study	Chief Investigator	Within 90 days (conclusion) Within 15 days (early termination) *The end of study should be defined in the protocol*	End of study declaration form available from the NRES website	Main REC with a copy to be sent to the sponsor

Summary of final Report	Chief Investigator	Within one year of conclusion of the research	No standard format However, the following Information should be included: Where the study has met its objectives, the main findings and arrangements for publication or dissemination including feedback to participants	Main REC with a copy to be sent to the sponsor

Appendix 2: Study Flowchart



Appendix 3: Study Gantt Chart



Appendix 4: Invitation Letter, Patient Information Sheet and Consent Form

< ENTER PATIENT ADDRESS>

<ENTER DATE>

Dear <ENTER PATIENT NAME>

Psychological Impact of COVID-19 on Intensive Care Survivors Study
AN INVITATION TO PARTICIPATE

We are conducting a research study investigating the psychological impact of surviving an intensive care admission due to COVID-19 on patients in the UK. You have been sent this invitation to participate because you were a patient in the <ENTER HOSPITAL NAME> intensive care unit where you were treated for COVID-19 infection.

Please read the patient information sheet provided carefully. If you have any questions or concerns in relation to the study, the local research team or the chief investigators will be happy to discuss these with you.

If the study team do not hear from you through the online survey system (a link and password is provided for you on a separate page), they will contact you by telephone to see whether or not you would like to take part in the study. There is no obligation for you to participate.

By following the link provided, you can let us know whether or not you would like to participate. If you indicate that you would like to take part, you will be asked to provide some basic information about yourself. Once you have answered these questions, you will be contacted via email or telephone to participate in the survey 3, 6, and 12 months after you were discharged from intensive care.

Thank you for your time in considering this request.

Yours sincerely,

<ENTER TRAINEE/CONSULTANT PI NAME>

Psychological Impact of COVID-19 on Intensive Care Survivors

PATIENT INFORMATION SHEET

What is the purpose of the study?

We are investigating the psychological impact of having been treated for Coronavirus disease 2019 (COVID-19). The purpose of this study is to improve our understanding of the psychological impact on patients of being diagnosed with COVID-19 and receiving treatment in intensive care. We are planning to ask you questions to assess symptoms of anxiety, depression and trauma that you may be experiencing. We will also ask you some questions which will enable us to identify potential risk factors for anxiety, depression and trauma following an intensive care admission due to COVID-19. We hope that by learning more about the psychological impact on people who have survived intensive care, we can improve our understanding and use the information to help inform healthcare planners about the number of intensive care survivors who might need psychological support once they go home.

Why have you been chosen?

You have been chosen because you had COVID-19 and were treated in intensive care.

Do I have to take part?

No, it is up to you to decide whether or not to take part. You are still free at any time to withdraw your consent without giving a reason. If you decide not to take part the standard of care you will receive will not be affected.

What happens if I agree to take part?

If you do decide to participate you will be given this information sheet to keep and will be asked to sign a consent form. The consent form can be completed online, over the telephone or on a paper form that we can post to you. If we have sent you this Invitation to Participate in the post and we do not hear back from you, a member of the local hospital team will contact you by telephone to see whether or not you are willing to participate in the study.

We will then ask you to complete questionnaires that ask you about symptoms relating to anxiety, depression and trauma. These questionnaires will be sent to you by the study team at the intensive care unit where you were a patient, at 3, 6 and 12 months after your ICU stay, where applicable.

You will be invited to complete these questionnaires online, but if you would prefer to complete a paper version of the questionnaire, or give your answers over the telephone to one of the study team members you can contact your local study team and they will organise this <ENTER LOCAL STUDY TEAM CONTACT DETAILS>.

We may contact your general practitioner to check your condition before sending out questionnaires. In addition to the questionnaires we send you, your local study team will collect information from hospital records about your past medical history and the support you received during your intensive care admission (e.g. whether you were on a ventilator).

What are the possible advantages and disadvantages of taking part?

Taking part in this study may contribute to improved treatment of patients with COVID-19 who are discharged from intensive care. The potential complications that may arise from this study are rare. We will be asking you questions about anxiety, depression and trauma symptoms. Sometimes, when people are asked to complete questionnaires about these topics, they can find this distressing. You may find that completing the questionnaire increases your level of anxiety, depression and trauma related to COVID-19, but this is uncommon. Should you be interested in support from others who have experience of what it is like to being a patient in intensive care, you can find a local support group and access other resources at the ICUsteps website: www.icusteps.org.

What if something goes wrong?

It is unlikely that anything will go wrong as a result of taking part in this study. If you have any concerns about this study you should contact the Chief Investigators (contact details below) who will do their best to answer your questions.

Would my taking part in this study be kept confidential?

Any information collected about you during the study will be kept strictly confidential and only be seen by staff involved in the study from the hospital trust where you were a patient in intensive care, the University of Liverpool, and people from regulatory authorities who ensure that studies such as this are carried out correctly. All of them will have a duty of confidentiality to you as a research participant.

Your contact details will only be held at the hospital where you were a patient in intensive care. We will keep your contact details for the duration of the study (2 years) in case we need to contact you.

Patient confidentiality will only be breached if you disclose information that may indicate harm to yourself or to others. We will try to contact you first and discuss this with you prior to contacting relevant agencies (e.g. your registered general practitioner) to inform them of concerns raised through this study.

What happens to the questionnaires completed during this survey?

Questionnaires will be completed online, via a system called REDCap; or by telephone with one of the study team members at the site where you were a patient recording your responses; or we can send you a paper version of the questionnaire.

REDCap is a secure online platform that is commonly used for surveys and study databases. The online questionnaires will be accessed via a link and password that is specific to you. Your responses will be stored using a unique participant number. Only the local study team will be able to tell that your participant number is linked to you, and when the study is finished and the data is analysed your responses will be anonymous. If you choose to complete the questionnaire online, we will ask you to enter your name and email address. These personal details will only be visible to the local study team, and will be deleted at the end of the study or if you decide to withdraw from the study.

If you request a paper version of the questionnaire, when you return the questionnaire one of the study team members will enter your responses into the online REDCap database, so that the information can be stored in the same format as questionnaires completed online.

All relevant documents related to the study will be stored confidentially and securely for 10 years following the end of the study. Members of the study management team will have access to stored data, and members of the study team at each site will be granted access to the data collected at their own site.

What will happen to the results of the study?

This study will take 2 years to complete. Publication of the results will follow shortly after this, through medical publications, websites and press releases. Anonymised results and updates on the study will be published regularly on the study website.

The data collected in this study may be used to support future research, but any data shared with third parties will be fully anonymised and cannot be traced back to the participant.

Who is organising and funding the study?

This study is being organised by a group of doctors and scientists led by Dr Alicia Waite who is a trainee and researcher in intensive care medicine at the University of Liverpool, and Professor Ingeborg Welters, who is an intensive care consultant, Research Lead at the Royal Liverpool University Hospital and a researcher at the University of Liverpool. The funding for this study comes from the Intensive Care Society and the Mersey School of Anaesthesia. The Sponsor of the study is the Liverpool University Hospitals NHS Foundation Trust.

Who has reviewed the study?

This research study has been reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been given a favourable opinion by the East Midlands – Derby Research and Ethics Committee.

What happens if I have any questions, concerns or complaints about the study?

If you have any questions about your participation in this study you should contact your hospital's Principal Investigator or a member of the research team. If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer. If you wish to complain formally, you can contact the Patient Advice and Liaison Service at your hospital: <INSERT TELEPHONE NUMBER FOR LOCAL PALS>.

We may ask you for feedback on the questionnaire itself, but this will be voluntary and will not be part of the study data.

What happens if I don't want to carry on with the study?

You are free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you receive. If you decide you don't want to continue in the study you will be given two options regarding any data already collected about you: 1) you can decide that any data already collected can be included in the study, or 2) you can decide that all data about you should be removed from the study. Removing your data from the study will only be possible before the data is analysed.

There are two timepoints at which the data will be analysed: the first analysis will be 6 months into the study, and the second will be at 18 months.

Any other questions?

If you have any questions that remain unanswered, the local study team member will be happy to answer these for you. If you require any further information you may contact the Chief Investigators (details below).

Chief Investigators:

Name: Dr Alicia Waite
Address: Intensive Care Unit, Royal Liverpool University Hospital, L7 8XP
Phone: 0151 706 2410
Email: alicia.waite@liverpool.ac.uk

Name: Professor Ingeborg Welters
Address: Institute of Life Course and Medical Sciences, University of Liverpool, L7 8TX
Phone: 0151 706 2410
Email: i.welters@liverpool.ac.uk

To find your nearest ICUsteps support group for intensive care survivors visit **www.icusteps.org.**

Thank you for taking the time to read this Patient Information Sheet.

CONSENT FORM

Title of Project: Psychological Impact of COVID-19 on Intensive Care Survivors

Chief Investigators: Dr Alicia Waite, Professor Ingeborg Welters

Centre Number: **Participant ID:**

1. I confirm that I have read the Patient Information Sheet dated 02/02/2021 (version 1.2) for the above study (or have had it read to me). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities and from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.

5. I agree to my General Practitioner being contacted, including any necessary exchange of information about me between my GP and the research team.

6. I agree to participate in the above study.

Name of participant	Signature of Participant	Date
Name of person taking consent	Signature of person taking consent	Date

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

Appendix 5: Welsh Invitation Letter, Patient Information Sheet and Consent Form

<CYFEIRIAD Y CLAF>

<DYDDIAD>

Annwyl < ENW Y CLAF >

Effaith Seicolegol COVID-19 ar y Sawl sy'n Goroesi Gofal Dwys

GWAHODDIAD I GYFRANNU

Rydym yn arwain astudiaeth ymchwil I effaith seicolegol goroesi'r uned gofal dwys ar gleifion yn y Deyrnas Unedig, ar ol iddynt datblygu COVID-19. Rydych chi wedi cael y gwahoddiad yma oherwydd eich bod chi wedi bod yn glaf yn <ENW YR YSBYTY> lle wnaethoch chi gael eich trin am haint COVID-19.

Hoffwn i chi ddarllen y daflen wybodaeth i gleifion yn ofalus i weld os hoffech chi gymryd rhan yn yr astydiaeth ymchwil. Os bydd gennych unrhyw gwestiynau neu bryderon mewn perthynas â'r astudiaeth, bydd y cyswllt ymchwil lleol neu'r prif ymchwilwyr yn fwy na pharod i drafod y rhain gyda chi.

Os na fydd tîm yr astudiaeth yn clywed gennych drwy'r system arolwg ar-lein (mae cyswllt a a cyfrinair ar dudalen ychwanegol) efallai y byddant yn cysylltu â chi dros y ffôn i weld os hoffech gymryd rhan yn yr astudiaeth neu pheidio. Does dim rhaid i chi gyfrannu.

Drwy'r cyswllt a ddarperir, gallwch adael i ni wybod os hoffech chi gymryd rhan yn yr astudiaeth neu pheidio. Os ydych chi'n hapus i gyfrannu, byddwn ni yn gofyn i chi am ychydig o wybodaeth sylfaenol amdanoch. Unwaith rydych chi wedi cwblhau y cwestiynnau yma byddwch yn cael eich cysylltu trwy e-bost neu'r teleffon i gwblhau arolwg am 3, 6, a 12 mis ar ol i chi gael eich rhyddhau o'r uned gofal dwys.

Diolch yn fawr am roi o'ch amser i ystyried y cais hwn.

Yr eiddoch yn gywir,

<ENTER TRAINEE/CONSULTANT PI NAME>

Seicolegol COVID-19 ar y Sawl sy'n Goroesi Gofal Dwys Wybodaeth i'r rhai sy'n cymryd rhan

GWYBODAETH I GLEIFION

Beth yw diben yr astudiaeth?

Rydym yn ymchwilio effaith seicolegol derbyn triniaeth ar gyfer afiechyd Coronafeirws 2019 (COVID-19). Diben yr astudiaeth hon yw gwella ein dealltwriaeth am yr effaith seicolegol ar gleifion sy'n cael diagnosis COVID-19 ac sy'n derbyn triniaeth mewn gofal dwys. Rydym yn bwriadu gofyn cwestiynau i chi i asesu symptomau gofid, iselder a thrawma y gallech fod yn eu cael. Byddwn hefyd yn gofyn rhai cwestiynau i chi a fydd yn ein galluogi i ganfod ffactorau risg posibl am ofid, iselder a thrawma yn dilyn derbyn claf i ofal dwys oherwydd COVID-19. Gobeithiwn trwy ddysgu mwy am yr effaith seicolegol ar y rhai sy'n goroesi gofal dwys, gallwn wella ein dealltwriaeth a defnyddio'r wybodaeth i helpu i hysbysu cynllunwyr gofal iechyd ynghylch y nifer sy'n goroesi gofal dwys a allai fod angen cymorth seicolegol unwaith y byddant yn mynd adref.

Pam y cawsoch chi eich dewis?

Roedd arnoch COVID-19 a derbynioch driniaeth mewn gofal dwys.

A oes rhaid i mi gymryd rhan?

Nac oes. Chi sy'n penderfynu a fyddwch yn cymryd rhan ai pheidio. Rydych yn rhydd i dynnu eich cydsyniad yn ôl unrhyw adeg a heb roi rheswm. Os penderfynwch beidio â chymryd rhan, ni fydd hyn yn effeithio ar safon y gofal a gewch.

Beth fydd yn digwydd os byddaf yn cytuno i gymryd rhan?

Os penderfynwch gymryd rhan, byddwch yn cael y daflen wybodaeth hon i'w chadw a gofynnir i chi lofnodi ffurflen gydsynio. Gellir cwblhau'r ffurflen gydsynio ar-lein, dros y ffôn neu ar ffurflen bapur y gallwn ei hanfon atoch trwy'r post. Yna, byddwn yn gofyn i chi gwblhau holiaduron sy'n gofyn i chi am symptomau'n ymwneud â gofid, iselder a thrawma. Caiff yr holiaduron hyn eu hanfon atoch gan dîm yr astudiaeth yn yr uned gofal dwys lle buoch yn glaf, ar 3, 6 a 12 mis ar ôl eich arhosiad yn ICU, lle bo'n berthnasol. Cewch eich gwahodd i gwblhau'r holiaduron hyn ar-lein, ond os byddai'n well gennych gwblhau fersiwn bapur o'r holiadur, neu i roi eich atebion dros y ffôn i un o aelodau'r tîm, gallwch gysylltu â'ch tîm astudiaeth leol a bydd yn trefnu hyn <ENTER LOCAL STUDY TEAM CONTACT DETAILS>.

Efaillai fyddwn ni yn cyfathrebu gyda eich meddyg teulu i wirio eich cyflwr cyn anfon y holiadur. Yn ychwanegol i'r holiaduron fyddwn ni yn anfon, mi fydd eich tîm astudiaeth leol yn casglu gwybodaeth o'ch cofnodion ysbyty am eich cofnodion meddygol a'r triniaeth wnaethoch chi dderbyn yn ystod eich cyfnod yn yr uned gofal dwys. (e.e. os oeddech chi ar beiriant anadlu am gyfnod)

Beth yw'r manteision a'r anfanteision posibl o gymryd rhan?

Efallai y bydd cymryd rhan yn yr astudiaeth hon yn cyfrannu at wella triniaeth i gleifion â COVID-19 sy'n cael eu rhyddhau o ofal dwys.

Mae'r cymhlethdodau posibl a allai ddeillio o'r astudiaeth hon yn anghyffredin. Byddwn yn gofyn cwestiynau i chi am symptomau gofid, iselder a thrawma. Weithiau, pan ofynnir i bobl gwblhau holiaduron am y pynciau hyn, gall hyn beri gofid iddynt. Efallai y gwelwch fod cwblhau'r holiadur yn cynyddu lefel eich gofid, iselder a thrawma sy'n gysylltiedig â COVID-19, ond mae hyn yn anghyffredin. Rydym wedi cynnwys gwybodaeth am adnoddau ac opsiynau cymorth a allai fod yn fuddiol os teimlwch fod angen cymorth pellach arnoch yn ystod yr astudiaeth hon neu ar ei hôl. Mae'r opsiynau hyn i'w gweld ochr yn ochr â'r daflen wybodaeth i gleifion.

Beth os aiff rhywbeth o'i le?

Mae'n annhebygol y bydd unrhyw beth yn mynd o'i le o ganlyniad i gymryd rhan yn yr astudiaeth hon. Os bydd gennych unrhyw bryderon ynghylch yr astudiaeth hon, dylech gysylltu â'r Prif Ymchwilwyr (manylion cyswllt isod), fydd yn gwneud eu gorau i ateb eich cwestiynau.

A fyddai fy rhan yn yr astudiaeth hon yn cael ei chadw'n gyfrinachol?

Bydd unrhyw wybodaeth a gesglir amdanoch yn ystod yr astudiaeth yn cael ei chadw'n gwbl gyfrinachol a dim ond staff sydd ynghlwm wrth yr astudiaeth o ymddiriedolaeth yr ysbyty lle buoch yn glaf gofal dwys, Prifysgol Lerpwl, a phobl o awdurdodau rheoleiddio sy'n sicrhau bod astudiaethau fel hon yn cael eu cynnal yn gywir, fydd yn cael gweld y wybodaeth. Bydd yn ddyletswydd ar bob un i barchu eich cyfrinachedd fel un sy'n cymryd rhan yn yr ymchwil. Dim ond yn yr ysbyty lle buoch yn glaf gofal dwys y caiff eich manylion cyswllt eu cadw. Byddwn yn cadw eich manylion cyswllt trwy gydol yr astudiaeth (dwy flynedd) rhag ofn y bydd angen i ni gysylltu â chi.

Byddwn ond yn mynd yn groes i gyfrinachedd cleifion os byddwch yn datgelu gwybodaeth a allai awgrymu niwed i chi'ch hun neu i eraill. Byddwn yn ceisio cysylltu â chi'n gyntaf ac yn trafod hyn gyda chi cyn cysylltu ag asiantaethau perthnasol (e.e. eich meddyg teulu cofrestredig) i roi gwybod iddynt am bryderon a godwyd trwy'r astudiaeth hon.

Beth fydd yn digwydd i'r holiaduron a gwblhawyd yn ystod yr arolwg hwn?

Caiff holiaduron eu cwblhau ar-lein, trwy system o'r enw REDCap, neu dros y ffôn gydag un o aelodau tîm yr astudiaeth ar y safle lle buoch yn glaf yn cofnodi eich ymatebion, neu gallwn anfon fersiwn bapur o'r holiadur atoch.

Bydd modd mynd at yr holiaduron ar-lein trwy ddolen unigryw sy'n benodol i chi. Mae'r ddolen hon yn cynnwys rhif unigryw i gyfranogwyr, a chaiff eich ymatebion eu storio gan ddefnyddio'r rhif hwn. Dim ond tîm yr astudiaeth leol fydd yn gallu gweld bod eich rhif cyfranogwr yn gysylltiedig â chi, a phan fydd yr astudiaeth wedi dodi ben, a phan gaiff y data ei ddadansoddi, bydd eich ymatebion yn ddi-enw.

Os byddwch yn gofyn am fersiwn bapur o'r holiadur, pan fyddwch yn dychwelyd yr holiadur, bydd un o aelodau tîm yr astudiaeth yn nodi eich ymatebion ar gronfa ddata REDCap ar-lein, fel bod modd i'r wybodaeth gael ei storio yn yr un fformat â'r holiaduron a gwblhawyd ar-lein.

Bydd yr holl ddogfennau perthnasol sy'n gysylltiedig â'r astudiaeth yn cael eu storio'n gyfrinachol ac yn ddiogel am ddeng mlynedd ar ôl i'r astudiaeth ddod i ben. Bydd aelodau tîm rheoli'r astudiaeth yn gallu cael gafael ar ddata sydd wedi'i storio, a bydd aelodau tîm yr astudiaeth ym mhob safle yn cael mynediad at y data a gesglir ar eu safle eu hunain.

Beth fydd yn digwydd i ganlyniadau'r astudiaeth?

Bydd yn cymryd dwy flynedd i gwblhau'r astudiaeth hon. Caiff y canlyniadau eu cyhoeddi'n fuan ar ôl hyn, trwy gyhoeddiadau meddygol, gwefannau a datganiadau i'r wasg. Mi fydd diweddariadau anhysbys o'r astudiaeth yn cael eu cyhoeddi ar wefan yr astudiaeth.

Gall data fyddwn ni yn casglu yn ystod yr astudiaeth gael ei ddefnyddio i gefnogi ymchwil yn y dyfodol. Fodd bynnag, bydd unrhyw ddata sy'n cael eu rhannu gyda partion arall yn ddienw, a methu cael eu olrhain yn ol i'r cyfranogwr.

Pwy sy'n trefnu ac yn ariannu'r astudiaeth?

Mae'r astudiaeth hon yn cael ei threfnu gan grŵp o feddygon a gwyddonwyr dan arweiniad Dr Alicia Waite sy'n hyfforddi ac yn ymchwilydd mewn meddygaeth gofal dwys ym Mhrifysgol Lerpwl, a'r Athro Ingeborg Welters, sy'n feddyg ymgynghorol gofal dwys, Arweinydd Ymchwil yn Ysbyty Brenhinol Prifysgol Lerpwl ac yn ymchwilydd ym Mhrifysgol Lerpwl. Daw'r cyllid ar gyfer yr astudiaeth hon gan y Gymdeithas Gofal Dwys ac Ysgol Anaesthesia Mersi. Noddwr yr astudiaeth hon yw Ymddiriedolaeth Sylfaenol GIG Ysbytai Prifysgol Lerpwl.

Pwy sydd wedi adolygu'r astudiaeth?

Mae grŵp annibynnol o bobl o'r enw Pwyllgor Moeseg Ymchwil, wedi adolygu'r astudiaeth ymchwil hon, i amddiffyn eich diogelwch, hawliau, ac urddas. Mae'r astudiaeth hon wedi cael barn ffafriol gan 'East Midlands – Derby Research and Ethics Committee'

Beth fydd yn digwydd os bydd gennyf unrhyw gwestiynau, pryderon, neu gwynion am yr astudiaeth?

Os bydd gennych unrhyw gwestiynau am gymryd rhan yn yr astudiaeth neu bryderon ynghylch y ffordd y cafodd ei chynnal, dylech gysylltu â Phrif Ymchwilydd eich ysbyty neu ag aelod o'r tîm ymchwil. Os byddwch yn awyddus i gwyno'n ffurfiol, gallwch gysylltu â'r Gwasanaeth Cyngor a Chyswllt Cleifion yn eich ysbyty ar <INSERT TELEPHONE NUMBER FOR LOCAL PALS>.

Efallai byddwn ni yn gofyn am adborth am y holiadur ei hun, ond mi fydd hyn yn wirfoddol ac ddim yn rhan o data yr ymchwil.

Beth fydd yn digwydd os nad ydw i'n dymuno aros yn yr astudiaeth?

Gallwch dynnu'n ôl o'r astudiaeth ar unryw adeg heb roi rheswm. Ni fydd hyn yn effeithio ar safon y gofal a gewch chi. Os penderfynwch nad ydych am barhau â'r astudiaeth, byddwch yn cael dau ddewis o ran unrhyw ddata sydd eisoes wedi'i gasglu amdanoch: 1) gallwch benderfynu bod modd i unrhyw ddata a gasglwyd eisoes gael ei gynnwys yn yr astudiaeth, neu 2) gallwch benderfynu y dylai'r holl ddata yn ymwneud â chi gael ei ddileu o'r astudiaeth. Bydd ond yn bosibl dileu eich data o'r astudiaeth cyn i'r data gael ei ddadansoddi. Mi fydd dau bwynt amser lle bydd y data yn cael ei ddadansoddi: yr un cyntaf am 6 mis, a'r ail am 18mis.

Mwy o gwestiynnau?

Os bydd gennych unrhyw gwestiynau heb eu hateb, bydd aelod o'r tîm astudiaeth leol yn fwy na pharod i ateb y cwestiynau hyn i chi. Os bydd arnoch angen rhagor o wybodaeth, gallwch gysylltu â'r Prif Ymchwilwyr (manylion isod).

Prif Ymchwilwyr ar y Cyd:

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Diolch yn fawr am roi o'ch amser i ddarllen y Daflen Wybodaeth i Gleifion.

FFURFLEN GYDSYNIO

Teitl y Prosiect: Effaith Seicolegol COVID-19 ar y Sawl sy'n Goroesi Gofal Dwys

Prif Ymchwilwyr: Dr Alicia Waite, Yr Athro Ingeborg Welters

Rhif y Ganolfan: **Rhif adnabod Cyfranogwr:**

1. Cadarnhaf fy mod wedi darllen y Daflen Wybodaeth i Gleifion ddyddiedig 02/02/2021 (fersiwn 1.2s) ar gyfer yr astudiaeth uchod (neu fod rhywun arall wedi'i darllen i mi). Rwyf wedi cael y cyfle i ystyried y wybodaeth, i ofyn cwestiynau a chael atebion sydd wedi fy modloni.

2. Rwy'n deall bod fy nghyfranogiad yn wirfoddol ac rwy'n rhydd i dynnu'n ôl ar unrhyw adeg, heb roi unrhyw reswm, a heb unrhyw effaith ar fy ngofal meddygol neu hawliau cyfreithiol.

3. Rwy'n deall y gallai unigolion o awdurdodau rheolaethol neu o'r Ymddiriedolaeth GIG edrych ar rannau perthnasol o fy nodiadau meddygol a'r data a gasglwyd yn ystod yr astudiaeth lle bo'n berthnasol i'm rhan yn yr ymchwil hon. Rwy'n rhoi caniatâd i'r unigolion hyn weld fy nghofnodion.

4. Rwy'n deall y bydd yr wybodaeth a gesglir amdanaf yn cael ei defnyddio i gefnogi ymchwil arall i'r dyfodol a gellir ei rhannu'n ddienw gydag ymchwilwyr eraill.

5. Rwy'n cytuno y gall fy Meddyg Teulu fod yn gysylltiedig â'r astudiaeth, gan gynnwys cyfnewid unrhyw wybodaeth angenrheidiol amdanaf i rhwng fy meddyg teulu a'r tîm ymchwil.

6. Rwy'n cytuno i gymryd rhan yn yr astudiaeth uchod.

Ticiwch y blwch hwn os hoffech dderbyn crynodeb o ganlyniadau'r astudiaeth:

Enw'r un sy'n cymryd rhan	Llofnod yr un sy'n cymryd rhan	Dyddiad

Enw'r un sy'n cymryd y cydsyniad	Llofnod yr un sy'n cymryd y cydsyniad	Dyddiad

Ar ôl ei gwblhau: rhoddir 1 i'r cyfranogwr, 1 i'r ffeil ar safle gwaith yr ymchwilydd; 1 i'w gadw yn y nodiadau meddygol.