Observational Protocol Template: UCLH/UCL Sponsored Studies
UCL/UCLH Research Office

Guidance

This protocol template is for use by **UCLH investigators to submit studies for UCL or UCLH Sponsorship** via the UCL/UCLH Research Office (RO).

Further information on which studies UCL or UCLH will sponsor can be found on its website.

This template is **not applicable** for all studies:

- deemed to be Clinical Studies of Investigational Medicinal Products (CTIMP)
- involving new Devices or Devices being used for a new purpose
- managed via a UCL Clinical Trials Unit (CTU)

This template has been developed to include all relevant regulatory, ethics and local policy requirements. The template contains all sections recommended by the Health Research Authority (HRA) for regulatory review by the HRA and the Research Ethics Committees.

Investigators may use other templates, but must ensure the sufficient level of detail is presented. Investigators wishing to do so are encouraged to read through this template. Text marked in **black** must be inserted into these protocols.

The RO will review each protocol submitted to ensure key sections and details are included before Sponsorship is formally agreed.

Instructions for use

Not all sections will be relevant for all studies. Each section can be modified or deleted as applicable to your type of study.

Instructions and explanatory text are indicated in **red** and should be removed or replaced in your protocol with the appropriate text.

Post sponsorship approval; any modification to the protocol should be annotated on the coversheet or in an appendix. The annotation should note exact words that are changed, the location in the protocol, the date the modification was approved by the relevant committee/parties, and the date it became effective.

Study Protocol Front Page

FULL PROTOCOL TITLE OF THE STUDY

Major surgery during the Coronavirus-19 pandemic – patients' experiences

SHORT STUDY TITLE / ACCRONYM

Chief Investigator:
Dr Cecilia Vindrola
Senior Research Fellow

Department of Targeted Intervention
Charles Bell House
43-45 Foley Street
London
W1W 7TY

Sponsored by:
University College London (UCL)

Protocol version number and date:
v0.8 12.07.2021

R&D / Sponsor Reference Number(s):
Edge 137951

Study Registration Number:
TBC

PROTOCOL VERSIONS

Version Stage	Versions No	Version Date	Protocol updated & finalised by;	Appendix No detail the reason(s) for the protocol update
Current	v0.8	12.07.2021	Dr Georgina Singleton	

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the Research Governance Framework 2005 (as amended thereafter), the Trust Data & Information policy, Sponsor and other relevant SOPs and applicable Trust policies and legal frameworks.

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

I (investigator) also confirm that an honest accurate and transparent account of the study will be given; and that any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature:  **Date:** 10/06/2021

Print Name(in full): Cecilia Vindrola

Position: Senior Research Fellow

On behalf of the Study Sponsor:

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

Print Name(in full):.....

Position:.....

STUDY SUMMARY

Identifiers	
IRAS Number	290891
REC Reference No	
Sponsor Reference No	Edge 137951
Other research reference number(s) (if applicable)	
Full (Scientific) title	Major surgery during the Coronavirus-19 pandemic – patients' experiences
Health condition(s) or problem(s) studied	Perioperative Services
Study Type i.e. Cohort etc	Qualitative
Target sample size	50
STUDY TIMELINES	
Study Duration/length	1 year
Expected Start Date	01/07/2021
End of Study definition and anticipated date	01/07/2022
Key Study milestones	Study Set-Up: Sponsor Review, UCL Research Ethics Committee (REC) review, Health Research Authority (HRA), NHS R&D approvals. Qualitative Data Collection Data analysis Write-up Dissemination of findings
FUNDING & Other	
Funding	N/A
Other support	Health Services Research Committee (HSRC) Churchill House, 35 Red Lion Square, London WC1R 4SG
STORAGE of SAMPLES (if applicable)	
Human tissue samples	N/A
Data collected / Storage	TP Transcription Limited 27 Old Gloucester Street London WC1N 3AX anna@tptranscription.co.uk
KEY STUDY CONTACTS	Full contact details including phone, email and fax numbers
Chief Investigator	Dr Cecilia Vindrola Department of Targeted Intervention

	Charles Bell House 43-45 Foley Street London W1W 7TY
Co-Investigator	Professor Ramani Moonesinghe Centre for Perioperative Medicine Research Department for Targeted Intervention Charles Bell House University College London 43-47 Foley Street London W1W 7TS ramani.moonesinghe@ucl.ac.uk ramani.moonesinghe@nhs.net
Student	Dr Georgina Singleton Centre for Perioperative Medicine Division of Surgery & Interventional Science, UCL 2nd Floor Charles Bell House 43-45 Foley Street London, W1W 7TS singleton.georgina@gmail.com 07817080166

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also has to be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether or not he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the RE of the end of the study, including the reasons for the premature termination. Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

OTHER:

KEY WORDS

SARS-CoV-2, coronavirus, COVID-19, Covid-19, perioperative, healthcare, health services, policy, large-scale, rapid, change, patient, experience

LIST OF ABBREVIATIONS

CI	Chief Investigator
COVID-19	Coronavirus-19
JRO	Joint Research Office
PI	Principle Investigator
PIS	Participant Information Sheet
REC	Research Ethics committee

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1 INTRODUCTION

The SARS-Cov2 (COVID-19) pandemic has led to considerable change to the care of patients requiring major surgery in the UK. The rapid changes that were required to perioperative services were unprecedented in their scale, speed of implementation, and impact on staff, patients and the wider healthcare service. The implemented changes are largely unevaluated, particularly qualitatively, and from a patient perspective. Using qualitative methods, this study will aim to gain an understanding of patients' experiences of the perioperative care provided during the pandemic. As a result of the pace of change, usual mechanisms for co-production with patients were largely swept aside. The findings of this study will be useful in identifying changes in the perioperative service that have been beneficial to patients. It is hoped that the results of this study will help in creating a framework that can be used by other institutions to enhance perioperative care pathways in the COVID-19 era and beyond. The study will also identify strategies that can be used within the NHS to support patient involvement in rapid change.

2 BACKGROUND AND RATIONALE

The COVID-19 pandemic has had a significant impact on the ways in which hospitals and services run. On 17 March 2020, as part of the response to COVID-19, NHS England and Improvement instructed the suspension of all non-urgent elective surgery, beginning on 15 April 2020 at the latest, for up to 3 months. Trusts were asked to prioritise, maintaining cancer and other clinically urgent care. [(1)] The need to provide elective cancer surgery and emergency surgery necessitated many changes to existing perioperative care pathways and services; many of these changes affected patients. Examples include the creation of separate pathways for COVID-19 and non-COVID-19 care, minimising hospital visits and the use of technology including virtual consultations. From this disruption comes an opportunity to re-design surgical pathways, retaining effective models of care and building on innovations. Patient and public involvement is a key feature in national healthcare policy [(2)] but owing to the rapidly evolving nature of the pandemic the usual mechanisms for this were largely bypassed. This study will explore the perceptions and experiences of patients with the service that they received during the pandemic. In addition this study will explore patients perceptions of how patient and the public involvement could be facilitated in the event of future rapid large-scale change within the NHS.

3 OBJECTIVES

3.1 Objective

- To explore patient experiences of the perioperative care pathway during the COVID-19 pandemic

3.2 Research Questions

- What are patients' experiences of receiving perioperative care during the pandemic?
- What are patients' views on how patient and public involvement can be facilitated within the context of rapid change in healthcare?

4 STUDY DESIGN

This is a qualitative study which will obtain data from semi-structured interviews. The study will sample patients who have undergone major elective cancer surgery under the care of University College London Hospital (UCLH) during the surge of the COVID-19 pandemic or during recovery phase. This may include patients who had NHS surgery in the independent sector but who remained under the care of UCLH. Interviews will focus on their experiences of undergoing major surgery during the pandemic specifically detailing the decision-making process surrounding their surgery, their pre-operative assessment, inpatient stay and post-operative recovery.

Interviews will be audio-recorded and notes taken by the interviewer.

The study aims to conduct 50 interviews. This number is based on the qualitative research model of 'theoretical saturation' [(3)]. The number indicated is based on the vast previous knowledge gained by the research team from conducting similar projects.

5 STUDY SCHEDULE

This study aims to start in July 2021 with data collection commencing in August 2021. The estimated data collection period is 6 months.

Month 1 - 2: study set-up
Months 2 - 9: data collection
Months 4 and 7: sharing of emerging findings
Months 10 - 11: final data analysis
Month 12: study wrap-up and submission of final report

The study duration will be one year but the involvement of the participants will be for the duration of the scheduled interview or observation.

6 CONSENT

The research team will be assisted by the local PI and clinical nurse specialists at University College London Hospital (UCLH) to identify patients who would be appropriate to recruit into this study. The research team will be assisted by the clinical team at University College London Hospital (UCLH) to identify patients who would be appropriate to recruit into this study. First contact to the potential participant will be made by a member of the participant's clinical team. If they agree to hear more about the study, the potential participant will then be contacted by one of the core research team (telephone or email) and provided with a Participant Information Sheet (PIS). The PIS details the background, purpose, design, risks and benefits of the study. The PIS will be provided to potential participants at least 48 hours in advance of any planned interview and participants will be given the opportunity to discuss the PIS (by telephone or email) with a member of the research team. If the potential participant decides to take part in the study they will be sent (by email or post) a consent form by a member of the research team and asked to sign and return this. If the potential participant prefers the use of post, a prepaid envelope will be provided for return of their consent form. Following receipt of the consent form the researcher will then proceed to arrange a telephone interview at a time that is convenient for the participant. Participants will be able to withdraw consent at any time before or during the interview. Data that has been collected already will be destroyed and not used for any analyses. No further data will be collected after the point of withdrawal.

7 ELIGIBILITY CRITERIA

7.1 Inclusion Criteria

- Patients undergoing elective surgery during the COVID-19 pandemic and the initial recovery phase (since 1st March 2020)
- Patients >18 years
- Patients able to provide informed consent

7.2 Exclusion Criteria

- Patients who lack sufficient fluency in English to undertake in-depth semi-structured interviews

8 RECRUITMENT

The research team will work in conjunction with the local clinical team to identify patients who would be appropriate to recruit into this study. A purposive sample will be obtained taking into account the patient's age, gender, type of operation and date of operation. Potential participants will be initially contacted by their own clinical team. If the potential participant agrees to hear more about the study they will then be contacted by the research team (by email or telephone) inviting them to take part in an interview. If the potential participant decides to proceed with the study we will ask them to sign a consent form. The participant will be given a choice as to whether the consent form is emailed or sent by post. If sent by post a pre-paid envelope will be provided for the participant to use to send the signed consent form back to the research team. After the research team have received the signed consent form, we will proceed to schedule an interview at a time which is convenient for the participant.

In order to reduce the burden on the clinical team, this study will not use the clinical team to fully recruit and obtain informed consent from the participants.

9 STATISTICAL METHODS

Participants will be chosen according to a purposive sampling strategy taking into account the patients age, gender, type of operation and date of operation.

10 PATIENT AND PUBLIC INVOLVEMENT (PPI)

We have the support of this study's lay representatives, specifically Irene Leeman and Jenny Dorey. They have provided feedback on the study protocol, materials and outputs, with particular focus on materials to be used in the recruitment process and in the patient interviews. They will provide ongoing review and feedback throughout the study and its dissemination. Both have reviewed the overall aims of the proposed research and are supportive.

11 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCL/UCLH Research Office, and deemed sufficient to cover the requirements of the study.

There will not be any associated NHS financial costs.

This is a fully funded student project through the UCLH Surgical Outcomes Research Centre.

12 DATA HANDLING AND MANAGEMENT

Audio recordings will be collected from participants in accordance with the consent form, PIS and the processes outlined in this protocol.

Interviewees will be consented for the interview to be recorded on a digital recorder owned by the research group.

Once the participant has consented to take part in a telephone interview they will be asked to provide their telephone number. The telephone number will not be stored beyond the interview.

The audio recording will be commenced just before the interview begins, and the interviewee will be informed when the recorder is switched off. No one will be identified by name on the recording. The researcher will securely store recordings on a UCL secure server before being sent for professional transcription.

TP Transcription Ltd (https://www.tptranscription.co.uk/) will be used for transcription of all interviews. It is a UK based company and therefore compliant with data protection legislature. Data will not be transferred out of the United Kingdom. This service is listed as an approved UCL transcription service. Transcripts will be transferred back to the research team securely. Following receipt of the interview transcript the audio recording will be destroyed. The transcript will be stored on a UCL secure server to which only the core research team (RM/ CV/ GS) has access.

Upon enrolling into the study, participants will be assigned anonymous participant codes rather than recording their names. The unique codes and a description of the participant's role will be stored in a password-protected file on a UCL secure server to which only the core research team will have access.

The personal data collected in the study include a participants email address and their name on the study informed consent form. Email addresses of participants and completed consent forms will be stored in a password-protected file on a UCL secure server to which only the core research team have access.

Any paper consent forms will be electronically scanned and stored on the UCL secure server. The paper copies will then be destroyed.

Data will not be transferred to any party not identified in the study protocol.

The CI and local researchers will process, store and dispose of audio and written participant data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act Act 2018 and any amendments thereto. UCL will act as the data controller of such data for the study.

Research data will be archived and preserved for a period of up to ten years after the study terminates, as per guidance from UCL. After this point, the data will be securely destroyed.

We will obtain permission from study participants to use data obtained from interviews in academic publications and reports. This will be a direct quote from interview transcripts. No participant will be identifiable directly.

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles.

13 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL/UCLH.

14 ASSESMENT AND MANAGEMENT OF RISK

This is an observational study and we do not foresee any major ethical issues. A few potential areas of concern are discussed below.

13.1 Data Confidentiality

We will seek consent for participation and a PIS will be provided which will explain how the data is collected and stored. With regard to confidentiality of data, the participants will be assigned a study code upon giving their informed consent to be part of the study. A single document (Excel spreadsheet), which is encrypted and only accessible by the CI and local researchers, will contain the participant's job role and the location of the site

where they work alongside their study code. No other personally identifiable information will be obtained from participants. Permission will be obtained to use direct quotes from transcripts. The identity of the participating hospitals will remain anonymous in all reports and publications. The risk for participants associated with any breach in confidentiality or failure to maintain data security should be extremely low.

13.2 Participant's Time
Telephone interviews will involve a time commitment from participants. The interviews are anticipated to be of approximately 30 minutes duration but will be scheduled at a convenient time for the participant. The research team are aware that the participants may still be recovering from surgery and will be flexible with regard to interview scheduling.

13.3 Discussion of Sensitive Topics
It is unlikely given that the focus of the interview is on perioperative care pathways but it is possible that participants may find the interview upsetting as they recall events surrounding their operation. In the event of this happening, the participants will be reminded that they can withdraw from the interview at any point and they will be directed to wellbeing support services.

15 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

15.1 Protocol deviations and notification of protocol violations

A deviation is usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the sponsor. The CI will monitor protocol deviations.

A protocol violation is a breach which is likely to effect to a significant degree –
(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study.

The CI and sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

15.2 Personal data breaches

A Personal data protection breach is defined as a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data (Information Commissioners Office, n.d.). In this study, minimal personal data will be collected to reduce the above risk.
In case of a personal data breach occurring, this will be reported immediately to the CI, Sponsor, Data Protection officer, and the JRO. Breaches will be documented in the Trial master file and will follow the procedures detailed by the sponsor.

15.3 Research related incidents and near misses

A near miss or a reportable incident is defined as: Any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components (Hasan, 2020):

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk of loss or damage

In this context, the JRO will be informed via incident reporting system ('Datix'). The JRO will liaise with the PI/CI to further advice.

15.4 Trust incidents and near misses

An incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.

Incidents and near misses must be reported to the Trust through DATIX as soon as the individual becomes aware of them.

A reportable incident is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a) It is an accident or other incident which results in injury or ill health.
b) It is contrary to specified or expected standard of patient care or service.
c) It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d) It puts the Trust in an adverse position with potential loss of reputation.
e) It puts Trust property or assets in an adverse position or at risk of loss or damage.

16 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the sponsor should she have concerns that have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

17 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files. The majority of this study has been designed and will be conducted by Dr Georgina Singleton as part of her PhD thesis at UCL.

18 INTELLECTUAL PROPERTY

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights ('IPR') to UCL and to disclose all such know-how to UCL with the understanding that they may use know-know gained during the study in clinical services and teaching to the extent that such use does not result in disclosure of UCL confidential information or infringement of UCL IPR.

19 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

20 ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study. On completion of the study, the CI confirms that she will archive the study master file at UCL for 10 years as per the UCL Records Retention Schedule. All the study data will be stored under a master file using the UCL secure server.

21 PUBLICATION AND DISSEMINATION POLICY

Key audiences for this research include healthcare professionals, healthcare managers, commissioners, policy-makers and patients. We will prepare various outputs, including reports (separate reports aimed at NHS colleagues and academic journals), infographics, presentations, and web-based seminars which will be tailored for different audiences. We will feed back results at intervals during the 12 months of study to ensure findings are used as quickly and usefully as possible. Participants will be offered the choice of accessing outputs.

22 REFERENCES

(1) NHS Chief Executive and NHS Chief Operating Officer. (2020) Letter to Chief executives of all NHS trusts and foundation trusts, CCG Accountable Officers, GP practices and Primary Care Networks and Providers of community health services, 17 March. Available from: https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/urgent-next-stepson-nhs-response-to-covid-19-letter-simon-stevens.pdf

(2) NHS England. (2017) Patient and Public Participation Policy. Available from: https://www.england.nhs.uk/wp-content/uploads/2017/04/ppp-policy.pdf

(3) Saunders B, Sim J, Kingstone T, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. Qual Quant. 2018;52(4):1893-1907. doi:10.1007/s11135-017-0574-