FULL PROTOCOL TITLE OF THE STUDY

LEGACIES AND FUTURES: VULNERABILITY, RESILIENCE, AND HEALTH AMONG LGBTQIA+ GESTATIONAL PARENTS AND THEIR NEONATES
(student study)

SHORT STUDY TITLE / ACCRONYM
LEGACIES AND FUTURES

Chief Investigator:
Dr David M Frost, PhD (Primary Supervisor)
Associate Professor in Social Psychology
Department of Social Science & Thomas Coram Research Unit
Institute of Education - University College London

Supported by:
Economic and Social Research Council (ESRC)
ESRC Grant Reference: ES/P000592/1

Sponsored by:
University College London (UCL)
UCLH/UCL Joint Research Office, part of the Research Directorate
4th Floor, West 250 Euston Road, London NW1 2PG

Protocol version number and date: *Version 3.3 (22/02/22)*

R&D / Sponsor Reference Number(s): 124858

Study Registration Number:
Z6364106/2020/02/50

PROTOCOL VERSIONS

Version Stage	Versions No	Version Date	Protocol updated & finalised by;	Appendix No detail the reason(s) for the protocol update
Current	**3.3**	**22/02/22**	**Kate Luxion PhD Candidate**	**Adding additional sites into the protocol Update on timeline Clarifying authorship of findings Addition of compensation for sub-study Correcting grammatical errors**
	3.2	06/10/21	Kate Luxion PhD Candidate	Adjustments in response to CAG review
	3.1	31/08/21	Kate Luxion PhD Candidate	Adjustments in response to ethical review by 21/LO/0551
	3.0	01/05/21	Kate Luxion PhD Candidate	Adjustments in response to REC and CAG review per notes included in the IRAS application
	2.0	05/10/20	Kate Luxion MPhil/PhD student	Adjustments response to CAG Advice Form, inclusion of participant notification media for recruitment
	1.0	03/08/20	Kate Luxion MPhil/PhD student	Ethics submission

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. 01/09/2020**

Print Name(in full): Dr. David M Frost

Position: Associate Professor in Social Psychology

On behalf of the Study Sponsor:

Signature:.  **Date: 02/09/2021**

Print Name(in full): Delasi Apraku

Position: Sponsorship Officer

STUDY SUMMARY

Identifiers	
IRAS Number	264198
REC Reference No	21/LO/0551
Sponsor Reference No	124858
Other research reference number(s) (if applicable)	Z6364106/2020/02/50
Full (Scientific) title	LEGACIES AND FUTURES: VULNERABILITY, RESILIENCE, AND HEALTH AMONG LGBTQIA+ GESTATIONAL PATIENTS AND THEIR NEONATES
Health condition(s) or problem(s) studied	Perinatal Health, Postpartum Health, Neonatal Health
Study Type i.e. Cohort etc	Cohort Observation Study (Epidemiology)
Target sample size	Main Quantitative Sample: 800 Nested Substudy Sample (Qualitative): 30
STUDY TIMELINES	
Study Duration/length	32 Months
Expected Start Date	1 March 2022
End of Study definition and anticipated date	This study is attached to a PhD, anticipated completion is when the study sample is reached and the findings are written up (by May 2024)
Key Study milestones	Study recruitment and enrolment: 1 March 2022 Data Collection: 1 March 2022 to 30 April 2023 Data Analysis: 1 March 2022 to 1 May 2024 Findings Write-up Due: 1 May 2024
FUNDING & Other	
Funding	ESRC/UBEL (tuition, maintenance, and consumables fund)
Other support	UCL/IOE Student's consumables fund
DATA COLLECTION & STORAGE	University College London - Project Data Safe Haven CI/Asset Owner: David M Frost PhD Student/Asset Administrator: Kate Luxion
KEY STUDY CONTACTS	Full contact details including phone, email and fax numbers
Chief Investigator and Academic supervisor:	Dr David M Frost, PhD (Primary Supervisor) Associate Professor in Social Psychology Social Research Institute & Thomas Coram Research Unit Institute of Education - University College London E-mail d.frost@ucl.ac.uk Telephone 020 7612 6403
Academic supervisor	Dr Melissa Whitten (Subsidiary Supervisor) Consultant in Foetal Medicine and Obstetrics Elizabeth Garrett Anderson Wing, University College London Hospital Lead for Undergraduate Women's Health UCL Medical School E-mail melissawhitten@nhs.net Telephone 08451555000 ext 2519
PhD Student and Study Coordinator	Kate Luxion, MFA MPH LCCE FHEA Thomas Coram Research Unit, Social Research Institute Institute of Education, University College London, London WC1H 6403 Email 1: stnvkll@ucl.ac.uk; Email 2: katy.luxion@nhs.net Telephone 07572869804

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring that arrangements are in place for the research team before a study begins, access to 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.

SITE COLLABORATOR(S): When necessary, site specific collaborators will assist with access to patient data for the purposes of recruitment and data collection. This can include primarily technical support and/or minimal site support (i.e., recruitment) as capacity and cost allows.

PHD STUDENT: As this project is centred around an educational outcome, the PhD student will be responsible for the majority of the tasks including, but not limited to: study design, recruitment, adherence to the protocol, data collection, analysis, and reporting through a PhD thesis recounting the details of the project. Under oversight by the CI, this role also includes notifying and reporting to the relevant parties any breaches or instances, as well as drafting the necessary final reports and publications that will be reported to the REC by the CI.

KEY WORDS

LGBTQIA+ reproduction, Pregnancy, Resilience, Vulnerability, Neonatal health

LIST OF ABBREVIATIONS AND GLOSSARY

AE – Adverse Event

Allostatic Load – A set of biomarkers that measure regulation of the cardiovascular, neuroendocrine, inflammatory, and metabolic system processes in the body.

Allostatic Overload – When dysregulation has taken place within the body due to the inability to return to a balanced state (i.e., clinical states of normalcy).

Antenatal – During pregnancy (i.e., before birth); interchangeable with prenatal.

Anonymisation – The process of removing personal identifiers, both direct and indirect, that may lead to an individual being identified.

AR – Adverse Reaction

Biological infertility – When mixed gametes (i.e., sperm and ovum) do not result in a live birth in an expected number of attempts.

Biosystem – A shortened term for biological system, representing linked processes within the body responsible for maintenance of certain bodily functions.

Bisexual – A term describing someone who is emotionally, romantically, and/or sexually attracted to someone of the same or different gender and/or sex from themselves. Synonymous with plurisexual.

BSUH – Brighton and Sussex University Hospital

CAG – Confidentiality Advisory Group

CI – Chief Investigator

Cisgender – An adjective used to describe someone who identifies the gender matching their sex assigned at birth

Cisheterosexual – A term for someone who is cisgender and heterosexual.

Construct – A concept or idea that is made up of smaller and/or simpler measurable components (i.e., subdimensions)

CRF – Case Report Form

CRO – Contract Research Organisation

DMC – Data Monitoring Committee

EPDS – Edinburgh Postnatal Depression Scale

Gamete – A non-gendered way of referring to sperm and eggs

Gay – A term describing someone who is primarily attracted (emotionally, romantically, and/or sexually) to members of the same gender; can be used by people of varying genders.

GAfREC – Governance Arrangement for NHS Research Ethics

GDPR – General Data Protection Regulation

Gender Nonconforming – A term describing someone who does not conform to expectation around gender in their gender identity, presentation, and/or social roles.

Gestational Patient – A pregnant person carrying the foetus they intend to birth and parent.

HTA – Human Tissue Authority

Hypothalamic-Pituitary-Adrenal (HPA) Axis – A protective feedback loop responsible for endocrine processes of the hypothalamus, pituitary gland, and adrenal glands

IB – Investigator Brochure

ICF – Informed Consent Form (electronic)

ICH – Imperial College Healthcare

Intersectionality – A theory explaining the complex interconnectedness of the aspects of self within the social world (i.e., gender, sexual orientation, race/ethnicity, class, etc.)

Intersex – A general term for variations in reproductive anatomy and/or sex characteristics, including genes, that differ from binary definitions of sex (male/female).

ISRCTN – International Standard Randomised Controlled Studies Number

KCH – King's College Hospital

Lesbian – A woman attracted to other women emotionally, romantically, and/or sexually.

LGB – Lesbian, Gay, Bisexual

LGBTQIA+ – Lesbian, Gay, Bisexual, Transgender, Non-binary*, Queer, Intersex, and/or Asexual; sometimes referred to as sexual and gender minorities. (*Not all non-binary individuals identify as transgender, so are included within the T and the "+" elements of the acronym, with more explicit inclusion in the definition to allow for this clarification.)

Minority Stress – Additional stressors felt by individuals with minority status within the social world.

NHS – National Health Service

Non-binary – A term describing someone that does not identify as male or female.

Perinatal – The weeks leading up to birth and weeks after birth.

PI – Principal Investigator

PIS – Patient Information Sheet

Plurisexual – A person who is sexually, emotionally, or romantically attracted to more than one sex/gender. Synonymous with bisexual.

Postnatal – After childbirth events relating to parent and infant, though typically used to refer to the infant; considered interchangeable with postpartum.

Postpartum – The period following childbirth, typically referring to the parent; considered interchangeable with postnatal.

Prenatal – During pregnancy; interchangeable with antenatal.

Pseudonymisation – A process that may involve replacing names or other identifiers which are easily attributed to individuals.

QA – Quality Assurance

QC – Quality Control

Queer – A term used by individuals to describe their own gender and/or sexual orientation; a slur reclaimed by the LGBTQIA+ community that was meant to demean them for being non-cisgender and/or non-heterosexual.

RCT – Randomised Clinical Study

REC – Research Ethics Committee

Resilience – A psychosocial construct defined as a phenomenon or process that is uses intrapersonal, interpersonal, sociocultural, economic, and political resources as a means of resistance or recovery from negative pressures/influences, such as stress, stigma, and discrimination. Often synonymous with protective factors.

SAR – Serious Adverse Reaction

SAE – Serious Adverse Event

Social infertility – Availability of only one gamete type in a partnership, requiring proof of biological infertility.

Structural Equation Modelling (SEM) – A quantitative method, using both observed and latent variables, used to test hypotheses within a model.

SOP – Standard Operating Procedure

SSI – Site Specific Information

Subdimension – A measurable, observable component of a construct.

TMF – Trial Master File

Transgender – An adjective used to describe someone who identifies as a gender other than the sex that they were assigned at birth.

UCLH – University College London Hospital

Vulnerability – A term used by bioethicists and researchers meaning a state of being and context in which power and/or interdependency effects the ability to act or react to internal and external stimuli, thereby diminishing tolerances of stress, stigma, and discrimination as it influences mental and biological processes. These processes may be relevant to both susceptibility to illness and/or the ability to recover from adverse health events. Often synonymous with risk.

CONTENTS

1 OVERVIEW OF PROPOSED RESEARCH

Patients using reproductive health services, like care during pregnancy (called antenatal care), are most often assumed to be heterosexual married women whose gender matched their sex assigned at birth (i.e., cisgender). Due to these assumptions, pregnancy care procedures are based on a sweeping assumption of who becomes pregnant and gives birth. This assumption is based on the pregnant person's gender and/or sexual orientation. As a result of this assumption, parents who are lesbian, gay, bisexual, queer, intersex, asexual, non-binary, and/or transgender (LGBTQIA+) can experience stress in the form of stigma, prejudice, and discrimination (i.e. "minority stress"). In the United Kingdom, there are 525,000 LGBTQIA+ potential gestational patients who may face this type of stress while receiving pregnancy care. That means that there is a preventable higher risk for pregnancy and birth complications caused by increased stress during pregnancy and daily life. These complications include macrosomia, pre-term birth, and low-birth weight. Preventable stress, also called minority stress, links to this increase in health problems outside of pregnancy as well. Since minority stress influences patient/parents' health, it is also called a risk or vulnerability. Resilience, or the ability to overcome stress and discrimination, can sometimes help improve health outcomes. However, little is known about which types of resilience can be helpful for LGBTQIA+ parents given their unique experiences of minority stress.

The planned observational study will investigate the ways in which experiences of minority stress and resilience in pregnancy care are associated with parent health and birth outcomes. A sample of pregnant patients (N=800) from maternity wards in and around London will take part through an online panel survey (completed twice) that will be linked to each patient/participant's electronic health records to create a quantitative dataset. Participant recruitment will focus on LGBTQIA+ pregnant patients (n=200). A matched comparison sample of cisgender, heterosexual pregnant patients (n=600) will also be recruited to take part from the same maternity. From the full sample, patient/parents from University College London Hospital will be invited to complete an at-home journal activity which will provide qualitative data on their experiences of minority stress and resilience. This smaller group (n=30). Results from this study can be used to inform LGBTQIA+ guidelines, training, and help make reproductive healthcare more inclusive.

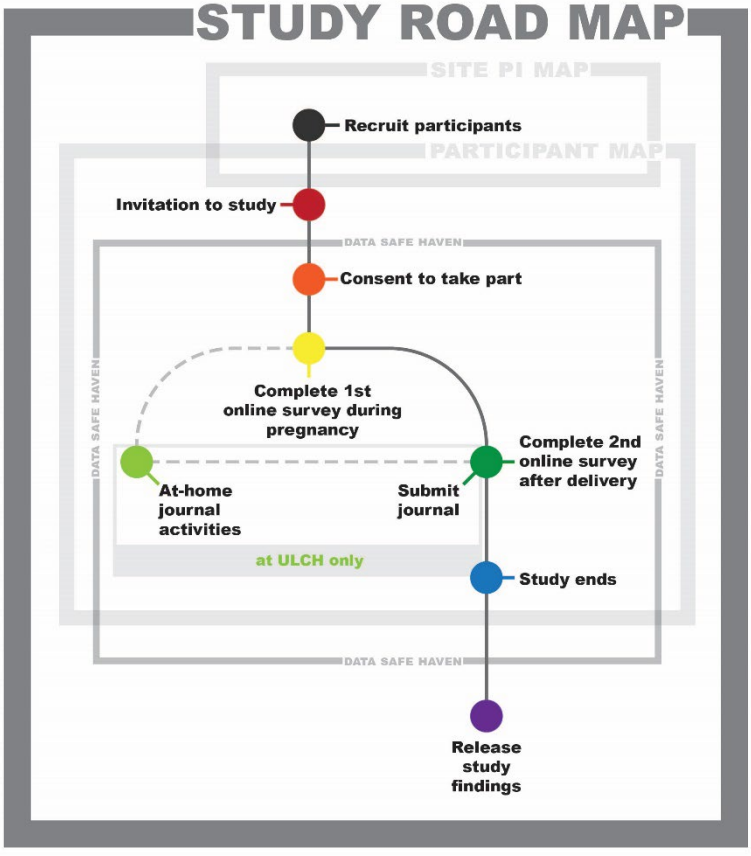


Figure 1 - Study Road Map for PIs and Participants

2 PROJECT IMPACT

The finding of this study will help to assess the impacts of prejudice and discrimination experienced in pregnancy and childbirth on the health of the gestational patient, and on the health of their infants (i.e., neonates). A better understanding of this impact has the potential to improve the care provided to pregnant patients, including updating guidelines of

care. This can also to help improve medical education and provider training to make sure that they are better equipped to care for LGBTQIA+ parents and to support them along with their families through the processes of pregnancy and childbirth.

3 BACKGROUND AND RATIONALE

Access to care while pregnant can be complicated and particular, especially since parents want what is best for their child even before they are born. For parents and soon-to-be parents who are lesbian, gay, bisexual, transgender, asexual, intersex, and/or queer (LGBTQIA+), they have the extra challenge of finding healthcare that is just as supportive of them as it is their peers who are heterosexual and cisgender (i.e., someone whose gender matches their assigned sex).[1–3] LGBTQIA+ parents having to make their way through pregnancy care with added risk, or social vulnerabilities, causing uncertainty and additional stress. This stress can lead to worse health[4–6] and potentially add preventable complications for LGBTQIA+ pregnant patients.[7]

This added stress is called minority stress, when people have more stress on top of the usual day-to-day stress for being a minority.[8] For example, booking forms and information pamphlets helpful to cisgender, heterosexual parents can be sources of exclusion by addressing the diversity of pregnant patients.[2,9] While some stress can be an annoyance, minority stress heightens stress levels to where there is a noticeable change in health and wellbeing because of social stigma.[6] Minority stress for LGBTQIA+ parents may also lead to additional fear of childbirth, because of uncertainty of how they will be treated while giving birth.[10]

For LGBTQIA+ parents, the impact of minority stress on their physical health and the health of the children they are carrying has yet to be studied. Discrimination's effect on pregnancy for racial minority parents confirms preventable stigma carries higher risks of pre-term and low-weight births.[11] The trauma of stigma during pregnancy is becoming an intergenerational problem, with pre-term infants being at higher risk of having pre-term births as adults.[11]

While facing these extra challenges, there are some possible means to reduce the impact of stress on parent health and wellbeing. This is evidenced in the form of resilience in the face of adversity and is linked to social support and community connectedness[8], among other protective factors. Previous research has focused mainly on the stressful experiences without accounting for potential positive and protective responses. This study will provide a better understanding of how parents are able to navigate and respond to stresses in antenatal care, while understanding what role resilience might play in the process, along with the resulting impact on their health and the health of their children.

4 RESEARCH QUESTIONS AND OBJECTIVES

4.1 Primary Scientific Questions

4.1.1 Gestational Patients

What role(s) do resilience and vulnerability play in the health and wellbeing of LGBTQ+ gestational patients, as compared to their cisgender heterosexual peers, during their antenatal care?

4.1.2 Neonates

What role(s) do a gestational patient's resilience and vulnerability play in the health and wellbeing of their neonate(s)?

4.2 Secondary Scientific Questions

4.2.1 Pregnancy

What narratives, relevant to vulnerability and resilience, are present in gestational patients' documentation of their antenatal care experiences?

4.2.2 Birth

What narratives, relevant to vulnerability and resilience, are present in gestational patients' documentation of their birth-related experiences?

4.2.3 Postpartum

What narratives, relevant to vulnerability and resilience, are present in gestational patients' documentation of their postnatal care experiences?

4.3 Primary Scientific Aim

An assessment of vulnerability and resilience resources on birth outcomes and neonatal health using Structural Equation Modelling and a journal activity.

3.4 Secondary Scientific Aim

Use of qualitative journals to have a better understanding of meaning-making by gestational patients' as they highlight concerns and experiences while navigating ante- and postnatal care.

4.5 Primary Non-Scientific Aims

4.5.1 Theoretical Novelty

Create a model of health and wellbeing using vulnerability and resilience as the primary constructs with the minority stress model and intersectionality as the key theories

4.5.2 Programme Requirements

Complete a dissertation to document the methodological and theoretical aspects of the study

4.5.3 Extended Impact

Planned peer-review publications and conference presentations to be completed from the project's theoretical, quantitative, and qualitative findings. This will also present in impact on antenatal care guidelines and improvements in electronic health records becoming more inclusive.

5 PATIENT AND PUBLIC INVOLVEMENT (PPI)

Members of the intended population were invited to comment on the proposed research process to improve the overall quality and value of the project and findings for future gestational patients. The following are how the community has been involved and will continue to be involved in this study.

5.1 Pre-study Questionnaire

A PPI questionnaire was circulated within parenting forums and groups, with participants asked to give their opinion about the study taking place along with some key aspects of the methods (i.e., recruitment). Over the four months the PPI questionnaire was open, fifty-seven (58) responses were gathered from LGBTQIA+ parents (n=36) and cisheterosexual parents (n=22) whose pregnancy care took/is taking place in the UK.

5.1.1 Support for the study

Responses to the PPI questionnaire were all in support of the study taking place, with 100% of parents in both groups agreeing that the study should take place. Several participants also shared why they felt the study is important and should happen. Here is a selection of quotes from them about the importance of the research (IDs are blinded):

So pleased to see this is going ahead as it could make such a difference to trans people experiencing pregnancy and starting families. As it is, I know many who opted out of starting a family based on the lack of available care and fear of transphobia from medical staff. -Response ID 8J10Z

I think this study is so important because the treatment received by the LGBTQ+ community is often subpar, discriminatory and degrading. Heterosexual couples also often don't realise just how different their experience is from ours so I think the results from studies like these are important to share too, so everyone realised the experiences of all those who carry children, regardless of orientation, race, sex, gender… -Response ID 4C80P

There is a huge research gap surrounding LGBTQ+ people and pregnancy/maternity care. The little research that does exist shoes poorer outcomes and dissatisfied clients. This needs to be addressed! -Response 6A88X

The current lack of inclusivity for LGBTQ+ patients/clients/service users as parents in the UK is undignified and more importantly, unsafe and dangerous. More work needs to be done to rectify this. -Response 1P65A

I think that this study is well needed, having experienced two very different pregnancies there are some big differences about being LGBT not least that there is almost always a story behind how the conception occurred. -Response ID 4Q99T

5.1.2 Recruitment methods

The results of the PPI questionnaire support recruiting participants via email prior to consent, with 74.13% of respondents in favour of the approach. Participants were also asked how many times they should be emailed before being marked as dissenting from further contact. Results suggest current patients should be emailed twice then marked as "no further contact" by the study. Other options were: email once (24.13%), email three times (15.51%), keep emailing (15.51%), and other (10.34%). These findings are laid out in the graphic below.

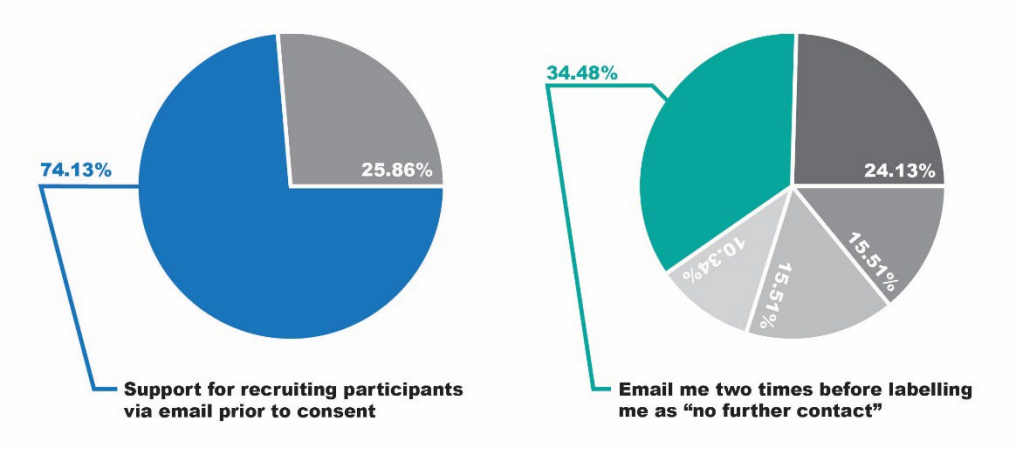


Figure 2 - Results from PPI Questionnaire on Frequency of Recruitment Emails

6 PEER AND REGULATORY REVIEW

The study has been peer reviewed under the requirements outlined by UCL as part of an educational programme, and in compliance of the proportionate and external review necessary for support by the NIHR Portfolio Adoption scheme. These reviewers come from both practice and academic settings as psychologists and/or educators. Their qualifications include lectureships in Health and Social Psychology in the United Kingdom, experience researching reproductive health and wellbeing, and working with and writing for patient populations. Their reviews, which are included as appendix 1, were incorporated as part of developing this protocol to improve accessibility and ensure the quality of the research.

The Sponsor has verified that the supervisor of the project has undertaken sufficient review of the protocol in line with the requirements of their department, along with the student researcher and subsidiary supervisor. The study has also been reviewed by three specialists outside of the study team to ensure the methods and procedures are clear and support by the literature to the level of care and rigour required prior to submission for ethical review.

The study was deemed to require regulatory approval from the following bodies (list). Each approval will be obtained before the study begins, once NHS approval is gained:

- Health Research Authority Research Ethics Committee
- Health Research Authority Confidentiality Advisory Group

Once the review process is completed with a positive result from the committees listed, there will be a letter of approval received that will be stored within the study files. Confirmation of the above ethics reviews using this letter will be submitted to UCL/IOE Ethics Review Committee in compliance with the notification procedures in place for student projects that are evaluated by non-UCL ethics review committees.

7 STUDY SCHEDULE

Study timelines are laid out to mirror the time restrictions present within full-time PhD study, limiting the overall study to a completion date of 1 May 2024, including data collection, analysis, and committee approval of a thesis document without further revisions. The study activities dates are:

- Study recruitment and enrolment: 1 March 2022
- Data Collection: 1 March 2022 to 30 April 2023
- Data Analysis: 1 March 2022 to 1 May 2024
- Findings Write-up Due: 1 May 2024

7.1 COVID-19 Contingency Plans

The study is designed for participation to take place online (with no requirement for direct interaction between researchers and participants) to limit any clinical impact and for the comfort and safety of participants. There are no alterations in the care received as part of the study.

If conditions change, placing restrictions on any form of clinical support (i.e., ability for sites to be local collaborators), the project can still unfold because of the training and access to electronic patient health records remotely that is being requested, the only implementation change being participant identification handled only by the CI and PhD student. In the instance where clinical antenatal services close at a taking part site, additional efforts for recruitment will take place at the remaining sites to compensate for the discrepancy in cases.

Additionally, there may be a staggered implementation across the sites depending on differences in supporting non-COVID studies again and the need to include more site to meet sample size

requirements. This will in no way impact the data, as participants will be matched to their comparisons (i.e., controls) based on site of antenatal care.

8 STUDY DESIGN

8.1 Population of Interest

The population of interest is LGBTQIA+ parents, between the ages of 18-49, who are currently pregnant and receiving care through an NHS hospital site taking part in the study. Cisgender heterosexual parents are included within the sample as a comparison group (see the section on Matching on page 19).

8.2 Sampling

8.2.1 Sampling Summary

- Target sample N = 800 (n = 200 LGBTQIA+ parents, n = 600 cisgender heterosexual parents)

8.2.2 Site Summary

The following sites have been selected as recruitment sites based on higher rates of LGBTQ+ residents in their catchment area. Sites will provide consistent access to current patient records at the maternity ward. No study activities involving contact between researchers and participants will take place on site at any of these locations:

- University College London Hospital NHS Foundation Trust (UCLH)
- University Hospitals Sussex NHS Foundation (UHS)
- Imperial College Healthcare NHS Trust (ICH)
- King's College Hospital NHS Foundation Trust (KCH)
- Homerton University Hospital (HUH)
- Barts Health NHS Trust (BH)
- Whittington Health NHS Trust (WH)
- Guy's and St Thomas' NHS Foundation Trust (GSTT)
- West Hertfordshire Hospitals NHS Trust (WHH)
- Kingston Hospital NHS Foundation Trust (KH)
- Royal Free London NHS Foundation Trust (RFL)

8.2.3 Sampling Frame

8.2.3.1 Sampling Frame Summary

- Sampling Frame pulling from 11 sites over 12 months: up to 75,652 gestational patients
    - Estimated LGBTQ+ parents in the sampling frame: 2,270
    - Estimated Cisgender, Heterosexual parents in the sampling frame: 73,382

8.2.3.2 Sampling Frame Construction

To construct a sampling frame for the project, a review of LGBTQIA+ population demographics in and around London was conducted.[12–15] Hospital Trusts with maternity services in catchment areas with higher percentages of LGBTQIA+ residents were selected for the study: 1) University College London Hospital NHS Foundation Trust (UCLH), 2) King's College Hospital NHS Foundation Trust (KCH), 3) University Hospitals Sussex NHS Foundation (UHS), and 4) Imperial College Healthcare NHS Trust (ICH). For the initial data collection phase, the study will start at UCLH, KCH, ICH, and BSUH.

Appendix 2, updated to include all 11 sites, provides a detailed account of sample-size calculation, with a project flowchart illustrating these steps in Figure 3 (page 19).

In order to address Covid-19 related delays, seven additional sites with maternity wards within the M25 were added. These sites include: 1) Homerton University Hospital (HUH), 2) Barts Health NHS Trust (BH), 3) Whittington Health NHS Trust (WH), 4) Guy's and St Thomas' NHS Foundation Trust (GSTT), 5) West Hertfordshire Hospitals NHS Trust (WHH), 6) Kingston Hospital NHS Foundation Trust (KH), and 7) Royal Free London NHS Foundation Trust (RFL).

A sampling frame including all eleven sites consists of 77,114 births annually, divided into a monthly rate for an average of 6,304 gestational patients per month (adjusting for births of multiples). London has the largest disclosed LGB population reported by the UK government at 3.1% with approximately .7% of the overall population identifying as transgender.[15,16] As transgender is a gender-specific umbrella term, transgender gestational patients can also be sexual minorities (i.e., lesbian, gay, bisexual, queer). Because of this overlap, the percentage of LGBTQIA+ parents being set at 3% was chosen as a conservative estimate, preferring to underestimate the number of participants at the planning stage. A 15% participation rate for LGBTQIA+ participants was chosen to account for any potential overestimations of eligible parents. The target sample requires 200 LGBTQIA+ parents as cases, with 600 cisheterosexual parents acting as controls; which is a purposive sampling approach with a 3:1 ratio of cases to controls (see Matching on page 21).[17] This sample size reflects a substantial enough number to support the proposed analysis (see page 29), with a power level of 0.8 and an estimated effect size of 0.3.[18] Based on these numbers, including the additional sites, a data collection window of approximately 12-months is necessary.

8.3 Identifying and Recruiting Potential Participants

At each site, a monthly report will be run by the PI or a supporting IT midwife. This report includes the relevant information of active antenatal patients with a gestational age higher than 16 weeks and lower than 36 weeks (i.e., with at least one month before their due date). Patients who have opted out of contact locally and nationally will be removed automatically as part of the search criteria. From this list, a selection of participants will be emailed by the researchers to be invited to take part in the study (see appendix 3 for selection process), this will be discussed in more detail in the section on recruitment below (see section 10). If interested, participants will follow a link in the email to a screener questionnaire (appendix 4) that will be used to assess eligibility. If patients screen eligible based on their responses to the screener, they will be emailed with an invitation to participate in the study and sent a link to provide consent and complete the study surveys.

8.4 Matching

LGBTQIA+ participants will be matched with cisheterosexual parents accessing antenatal services at the same care site. Matching cases across the groups controls for potential confounders, including geographic and temporal differences that would otherwise not key to the overall analysis as individual variables.[19] A screener questionnaire (appendix 4) will assist with recruitment and the case-matching necessary to complete the sample. Variables used for matching cases are: site of antenatal care (by hospital trust), planned location of birth (as "at home", Birth Centre/Midwifery Unit", and "in hospital"), and time of care received using participant's due date (i.e., temporal differences in care). A minimum of twelve current patients will be contacted for each confirmed LGBTQIA+ participant with two-fold purpose. First, the ideal would be for a minimum of three controls per case, so a higher number of patients contacted allows for feasibility despite a potentially low response rate (i.e., 25%). Concurrently providing a staged process to approach the fewest number of patients in the sampling frame as possible. Taking these potential barriers into consideration should allow for a matched sample of at least 800 gestational patients with a 3 to 1 ratio of cases to controls.

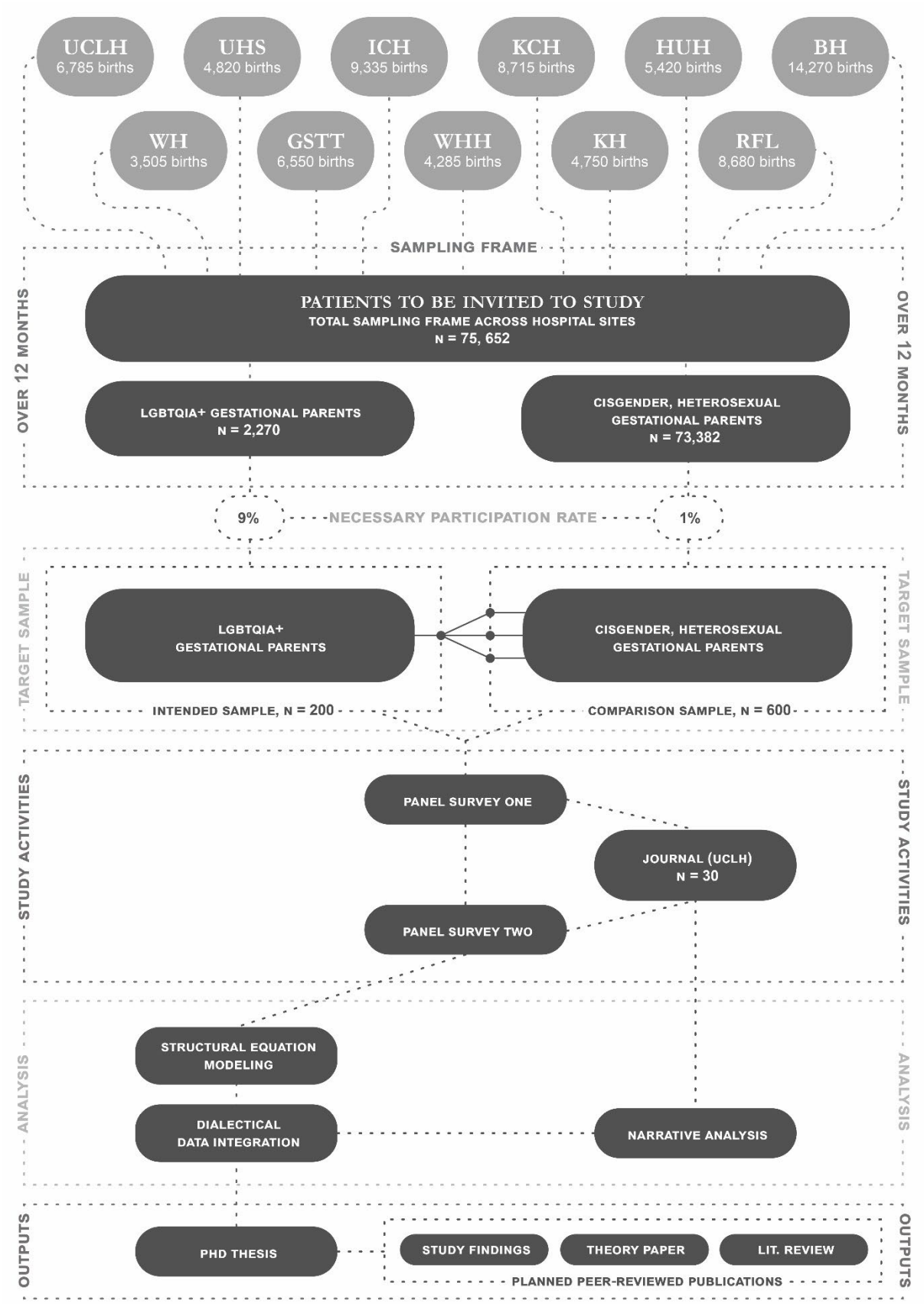


Figure 3 - Sampling Frame and Project Methods Flowchart

9 ELIGIBILITY CRITERIA

Electronic health records from maternity wards taking part in the study will serve as a sampling frame for the study. This includes recruitment and screening, focusing on LGBTQ+ patients who are receiving antenatal care. While the eligibility criteria will guide the screening and recruitment process, it is important to clarify that any discussion of exclusion based on consent refers only to the electronic consenting that will take place after the screening process mentioned in the section on recruitment.

As part of a multi-stage sampling approach, patients' records will be reviewed for the recruitment of a primary patient group which will get paired with matched-case respondents. Respondents in the primary patient group are defined as those who have disclosed themselves to be lesbian/gay, bisexual, transgender, gender non-conforming, and/or non-binary (or any other label under the LGBTQIA+ umbrella) within their electronic health records or the study screener. Case-matched respondents will draw from the sampling frame to provide a comparison group made up of cisgender heterosexual women. Utilising matched cases will also allow for contextualising the findings in the broader cisheteronormative literature on pregnancy and birth.

9.1 Inclusion Criteria

Patients must meet all of the following in order to be eligible for the study:

- Legal adult of reproductive age (18-49)
- Identifies as a lesbian, gay, bisexual, queer, nonbinary, intersex, and/or transgender (or cisgender and heterosexual for comparison sample)
- Currently pregnant and receiving antenatal care at one of the 4 study sites

9.2 Exclusion Criteria

Patient ineligible for the study:

- Any pregnant persons under the age of 18
- Pregnant individuals using site locations for Urgent Care, A&E, non-antenatal services only

9.3 Language Limitations

The project can only be offered in English due to the limited resources and time constraints inherent to this PhD research. Further, the survey questions and measures to be used have been developed and validated in English only. Were these to be translated, they would need to be validated in the new languages in a separate study. For both feasibility pertaining to time and cost, the surveys can only be made available in English.

9.4 Known Risks

The study, inclusive of the sub-study, does not alter the participants' care in any way. There are only minimal risks associated with participation in the study.

- Participants may experience negative emotions in response to some of the topics of the study questions (e.g., about discrimination, stigma, and stress). However, the nature of such questions is similar to topics discussed in everyday conversations with family and friends and typically covered in the news and social media, and therefore do not represent more than minimal risk. In order minimize potential for negative emotions, participants will be told about the nature of the questions in the participant information sheet, and they will be provided with information on counselling resources should they need additional support.
- There is potential risk to loss of confidentiality due to the nature of online participation from participants' homes and other locations of their choosing. This will be minimized by including instructions in the participant information sheet to ensure no one can see the screen of their device and that they clear their browser history after participation.

9.4.1 Experiences of Stress

In the instance of participants experiencing stress, they have been advised in the main study PIS and in the sub-study PIS to pause whatever activities they are doing and to seek out support through the resources provided in section 18.1.1. This information is also made available to participants via the PIS for both the main and sub-study as an answer to the question "What if I feel like I need help or support?". As support for stress is outside of the scope of the study team, signposting to these resources is the main approach to ensure that participants who experience stress are able to connect with qualified professionals.

9.5 Loss of Capacity

Because of the methods of the study, it will not be possible to track whether participants lose capacity to participant. This is due to it not being possible for the research team to monitor capacity, meaning that continued capacity will be assumed. The data collection is planned to take place online in a participant's own home (or secure location of their choosing). The team will not be meeting with the participants face-to-face and hospital staff may not be aware of participation. Thus, it falls outside the study team's scope to assess capacity clinically during participation.

10 RECRUITMENT

10.1 Recruitment Summary

- Potential participants will be identified from Electronic Health Records in study sites
- Potential participants will be emailed inviting them to complete a screener questionnaire to assess eligibility
- If eligible based on response to screener questionnaire, an invitation to participate in study survey will be sent

10.2 Recruitment Process

The recruitment process requires multiple approaches because of differences between the maternity ward sites. These differences were deemed necessary after talking with each site PI and members of the midwifery team, including clarifying the capacity available to help with in-clinic recruitment.

Participants that are potentially eligible for recruitment will be identified through their patient records. Through email contact, an invitation and screening survey will be sent to current patients to introduce the study to them. The recruitment email also includes a link to the PIS (as a web page and PDF, see appendix 5a and 5b) along with other details provided in the study's website: http://www.homepages.ucl.ac.uk/~stnvkll/. The emails themselves will be sent out by the Kate Luxion, the PhD candidate. As costing and capacity allows at each of the sites, a contact slip will be provided to clinical staff for them to use for recruitment. Details about the study, including the patient information sheet, will be made available online (http://www.homepages.ucl.ac.uk/~stnvkll/PIS) in order to support the participants.

As is common in survey research, recruitment will take place prior to consent as recruitment includes informing potential participants about the study taking place. To ensure that the study is in compliance with GDPR, support from the Confidential Advisory Group (CAG) is being sought through a concurrent application (21CAG0149). CAG support makes sure that all processes meet the necessary requirements under section 251, which stipulates it is legal to use patient contact information for recruitment purposes prior to consent in instance of health and social research.

10.2.1 Summary of Recruitment Methods

- Email (appendix 6) to current antenatal patients
  - with link to screener questionnaire (appendix 4)
- In-clinic recruitment (as capacity allows)
  - Study pamphlets
  - In-clinic posters
  - Recruitment Script
  - Contact slip
- Social Media Marketing
  - Twitter
  - Facebook
  - Instagram

10.3 Patient Data and Communication Policies

This recruitment method has been informed by NHS communication policies, PPI activities (section 5), and through discussion with the site PIs and research midwives across the sites.

10.3.1 NHS Patient Data Policies

Communication policies for research are shaped by NHS-level policies. According to NHS policy, patients registered within the health system can expect to have their data used for research or research communications, unless they chose to opt-out. This information is made available by the NHS to patients online at https://www.nhs.uk/your-nhs-data-matters/. Within this area of the NHS website, around who will have access to confidential patient data, further detail is provided to patients. This list includes university researchers, along with other researchers and organisations.[20]

10.3.2 Research Sites Patient Data Policies

The hospital sites, as research hospitals, apply the same policy to their records and make these policies available in various formats for patients. These policies are meant to make patients aware that their data may be used for research, requiring opting out for data to not be used. The use of patient data, as mentioned in the policies, may include invitations to participate in research being undertaken in partnership with the Trust. In all instances, it has been confirmed by the PIs and the research and development offices of each site that the following information is provided to patients in the formats mentioned.

10.3.2.1 University College London Hospital NHS Foundation Trust

University College London Hospital Trust's policies are similar to general NHS policies (section 10.3.1), in that patients are informed through various posted policies that their patient data may be used for research, with the option to opt-out if they wish their data to not be used. In the "Cookies & privacy" notice, the Trust notifies patients that their data may be used for clinical research, among other uses.[21] This information is also is discussed on another page of the Trust's website, under "Protecting patient data in research – security, storage, and consent", stating the use of patient data by researchers may include use without consent in the context of the research in question.[22] The notice also clarifies that projects who do access data in this way will have done so following procedures and precaution under the oversight of the Confidentiality Advisory Group.[22] As mentioned above, information is also provided on both these pages on how patients can object or opt-out of their data being used[21,22], meaning that patients are both notified and given the option to restrict access to their patient information being used in the proposed manner. Thus, patients who has restricted use of their data can be excluded for this site.

10.3.2.2 Imperial College Healthcare NHS Trust

Imperial College Healthcare details the use of patient data within their patient privacy notice, as both a document and a webpage.[23,24] The notice clarifies that while the Trust minimises the sharing of personal data that it may be shared outside the care team and outside the Trust for research purposes, including identifiable data.[23(p1)] As part of this same notice, patients are informed how they can opt-out of their data being shared and restrict access, meaning that patient data accessed can be limited to exclude patients who have opted out of data sharing at both the national and local levels.[25]

10.3.2.3 University Hospitals Sussex NHS Foundation

Use of patient information is clarified on the Brighton and Sussex University Hospitals NHS Trust's website. The site explains that patient health records, inclusive of name and contact information, may be used in conducting health research (under "Why we collect information about you"), separately emphasising within the next few lines that the Trust is a "research-active Trust".[26] Use of personal data prior to consent within medical research is also discussed in the leaflet "Your Personal Information"[25] that is made available by the Trust and accessible via the same webpage discussed earlier under the heading "Further information"[26]. In this same section, patients are signposted to Information Governance if they require more information and links to the patient leaflet, which notifies them of their right to restrict use of their patient data.[26] With the pamphlet linking patients back to the NHS data policy (discussed in section 10.3.1). Further discussion of compliance with the national data opt-out policy in the patient leaflet[25] clarifies that patients at this site can be excluded if they have opted-out or restricted use of their data during recruitment.

10.3.2.4 King's College Hospital NHS Foundation Trust

Patients are notified about use of their patient data, including use related to research, via the Trust website. The website states that their routinely collected information may be "re-used for research purposes".[27] Patients are also given the link to the Health Research Authority's website[28] which links back to the NHS policy (discussed in section 10.3.1) which states patient data can be for research purposed, and that for data to not be used patients must opt-out.[20,28] These resources also provide information to patients on how to opt-out from their data being used for research at the organisational and national levels.[27,28] As such, it is possible to ensure patients who restricted use of their data via opting out can be excluded for this study site during recruitment.

10.3.2.5 Barts Health NHS Trust

Barts Health and NHS Trust notifies patients by describing how they use patient data within their Trust-wide privacy notice.[29] Within this same documentation, patients that do not want their data used for research are signposted to the NHS data policy (as discussed in section 10.3.1).[29] The Trust's corporate research sharing policy is also publicly available and details use of data, including HRA/REC policy compliance and Section 251 approvals.[30] Based on the policies available, no data will be accessed when service users have opted out of data use for research.

10.3.2.6 Guy's and St Thomas' NHS Foundation Trust

Guy's and St Thomas' provides service users with a detailed breakdown of how their data might be used for research on a section of their webpage titled "Use of Data".[31] This webpage also signposts service users to the national opt-out if they do not wish for their data to be used for research. As such, service users have been notified about data use for research and no data will be accessed for

service users who have registered with the national opt-out scheme (i.e., NHS data policy in section 10.3.1).

10.3.2.7 Homerton University Hospital NHS Foundation Trust

Homerton University Hospital's privacy notice online notifies service users that their patient data may be used for research.[32] This information is also available in a PDF format.[33] In both instances, patients who do not want their data used for research are signposted to the national opt-out scheme (as described in section 10.3.1).[32,33] Thus, it will be possible to exclude restricted patient data from reports at this site, along with confirmation that patients are notified of how their data may be used.

10.3.2.8 Kingston Hospital NHS Foundation Trust

Within the Trust's privacy notice, service users are made aware of uses for their patient data with special attention paid to use for research that includes discussions of CAG approval for some projects.[34] In kind, patients are signposted to the National Opt-out scheme (section 10.3.1) if they do not wish for their data to be used for research or planning.[34] Service users who have restricted use of their data will thus be kept from reports for this site, confirming because patient notification and use of only unrestricted data.

10.3.2.9 Royal Free London NHS Foundation Trust

Service users are told how their data is used within the Trust's privacy notice. This main notice includes clarifying that patient data may be used for research.[35] A link to the National data opt-out scheme (section 10.3.1) is included at the end of the main notice, along with a link to a more detailed research privacy notice. This detailed research-centred notice talks through both data use and the rights of the patient, including the right to restrict the use of their own data or object to it being used.[36] Both forms of data use limitations signpost to Trust-level contacts that handle processing related requests. Presence of these policies confirm that there is proper notification of service user about data use and the ability to ensure exclusion of patients who have opted out of their data being used for research.

10.3.2.10 West Hertfordshire Hospitals NHS Trust

Patients using services at West Hertfordshire Hospitals can learn about how their data is used by the Trust by reading the local privacy notice.[37] This notice includes statements that patient data might be used for research. There is also signposting to the NHS England and NHS Digital websites for more information. Patients are also told about their rights around use of their data and signposted to speak to their clinician if they object to their data being used in particular ways or if they wish to withdraw consent. This document confirms that there is a patient notification process in place about data use for research, as well as the ability to ensure that only unrestricted data will be included within reports for recruitment.

10.3.2.11 Whittington Health NHS Trust

The Trust's privacy notice includes information about how patient data may be used for research, as well as signposting patients to the national opt-out scheme (section 10.3.1) if they wish to restrict the use of their data.[38] This notice confirms that there is a patient notification in place, as well as confirmation that patients at this Trust have been made aware of data use opt-out mechanism. Thus, any reports run by this site will be able to exclude patients who have stated that they do not want their information used for research.

10.3.3 Legal Use of Email Addresses

In addition to NHS and local organisational policies, this approach has been made possible through section 251 of the National Health Service Act 2006, supported by the data collected through the PPI activity reported in this protocol's section 11. This is important to note as many of the above policies highlight that there are justifications to access being granted to researchers prior to consent. Additionally, this project is deemed as having benefit to public interest, both in definition and in the public's opinion (as discussed in PPI activities in section 5).

10.3.4 Confidential Advisory Group Precedent Set Categories

The proposed method of recruitment also falls under the Precedent Category 1 of the Confidential Advisory Group pathways. The categories denote when a scenario requiring CAG oversight is considered to be "commonly-arising". This precedent is used is used for participant identification, allowing for access to data "on potential participants in order to send them study invitations or surveys."[39]

10.4 Recruitment and Notification Methods

In order to recruit patients that are actively receiving antenatal care, patient records will be accessed for patient names, gestational due dates, and email addresses. Development of these recruitment methods have been done in consultation with the site PIs and the supervisory team, with further advice provided through the patient and public involvement activities discussed earlier (Section 5). The following details the pathways and steps for recruitment. Methods for notifying patients about the study will include two pathways: contact via email with a screener questionnaire and notification done by the care team, in compliance with section 251.

10.4.1 Pathway One: Recruitment via Email

The first pathway to recruitment is via email. This will take place by the study coordinator emailing current antenatal patients to inform them of the study and to invite them to complete the screener questionnaire.

To access the necessary email addresses, a report will be run each month by each site's contact person (i.e., research or IT midwife) to provide the eligible email addresses to be contacted. This list, in the form of a report, will be composed of active antenatal patients prior to 36 weeks gestation. Only patients whose data can used for research will be included within these monthly reposts (as explained in 10.3.2). Once generated, the reports will be securely uploaded to data safe haven where it will only be accessed by the study team. When patients are emailed an invitation to the study screener it will be sent to them via REDCap, the survey platform on the data safe haven. These emails will be sent out in small batches to use the minimal number of patients' emails each month, as discussed in the email protocol in appendix 3.

Along with a link to the screening questionnaire, the email provides information on how to remove themselves from the study contact list and how to opt-out of their information being used for research without their consent.

10.4.1.1 Dissent Mechanism

In the case that there is no participation or reply, a dissent mechanism is in place to keep emails to patients minimal. After a potential participant has been emailed twice, with no response or engagement, they will be marked as "no further contact". A list of excluded emails will be kept in a secure file on the data safe haven. This list will be kept until the end of the study, to make sure that they are excluded from further contact in the case of another pregnancy during the recruitment window.

10.4.2 Pathway Two: Notification methods

A concurrent, and secondary, pathway will be done by clinical staff as capacity allows. In part, this pathway is to address the need for additional notification methods to allow for there to be an alternative to the study team using email addresses if and when it becomes feasible at each location. To clarify, this is a list of the materials that will be made available to study sites, how sites use them may vary (i.e., over the phone bookings vs. face-to-face discussions, etc.). In addition to what is listed here, there may be routine recruitment approaches sites use to share information about ongoing studies with service users (i.e., active study lists, text alerts, notification during appointments, etc.). The following materials have been created and compiled to support recruitment and will be made available to all sites involved within the study to serve as these notification materials.

10.4.2.1 In-clinic Materials

A packet of materials has been put together that will be shared as digital files which can readily be printed on-site as they are needed (see appendices 7-10). The list of materials necessary to create has been generated based on the consultations held with the site PIs and the midwifery team members. The materials below are meant to support and not limit the methods the care team may choose to use for recruitment (when there is capacity). These study-related materials include:

- A tri-fold pamphlet for parents and providers with a QR code linking to the online PIS
- An A4 poster for being posted in-clinic with QR code
- A provider script for introducing the study to patients
- A contact slip to be used for both permissions to contact for recruitment and opting-out

10.4.2.2 Social Media Marketing Materials

Social media posts have been created for Twitter, Facebook, and Instagram (appendix 11) after consulting with the hospital sites. Full-size images will be provided to each site, with a preview of the images shared here.

10.4.2.2.1 Image Captions

This caption will be used across all the social media platforms:

Pregnant?

We are recruiting LGBTQ+ and heterosexual pregnant patients for a student study on pregnancy and birth outcomes. If you are interested in participating in the study you can ask your care team for more information. Check out the study website at https://www.homepages.ucl.ac.uk/~stnvkll/

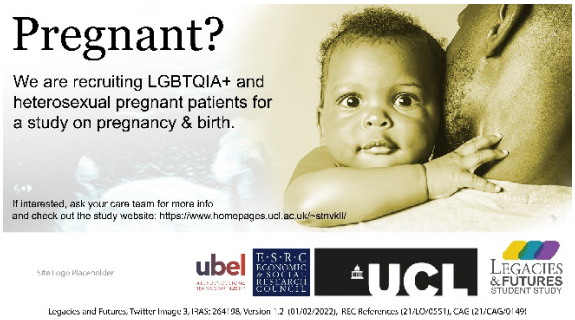
In addition to these social media posts, this study is using email addresses from patient records to recruit participants. To keep your email from being used, you can notify the study team that you do not wish to be emailed by filling out the opt out form at tinyurl.com/yck6twfu or by calling +44 20 3108 4358.

10.4.2.2.2 Twitter Images

Legacies and Futures, Twitter Image 1, IRAS: 264198, Version 1.2 (01/02/2022), REC References (21/LO/0551), CAG (21/CAG/0149)

L+F Twitter 1.jpg

L+F Twitter 2 v1-2.jpg



L+F Twitter 3 v1-2.jpg

10.4.2.2.3 Facebook Images

L+F Facebook 1 v1-2.jpg

L+F Facebook 2 v1-2.jpg

L+F Facebook 3 v1-2.jpg

10.4.2.2.4 Instagram Images

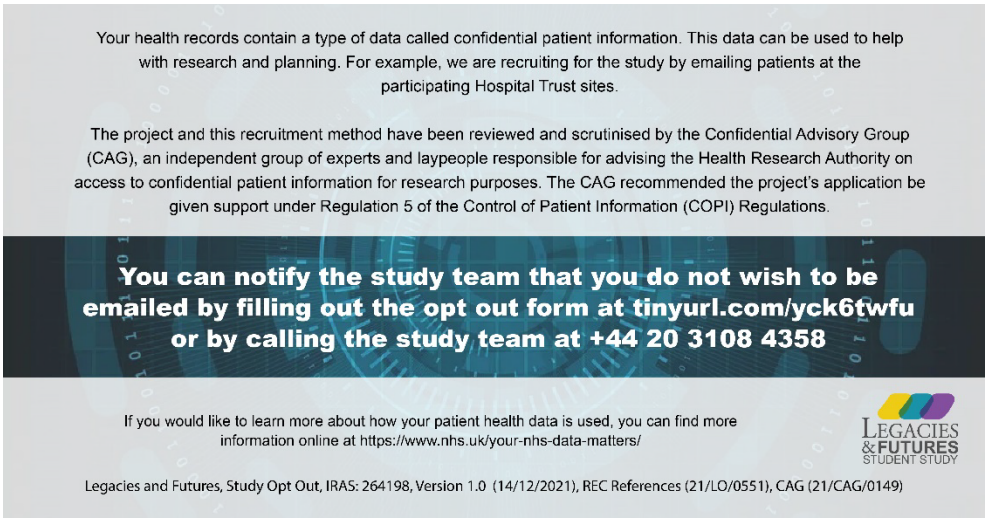
Legacies and Futures, Instagram Image 1, IRAS: 264198, Version 1.2 (01/02/2022), REC References (21/LO/0551), CAG (21/CAG/0149)

L+F Instagram 1 v1-2.jpg

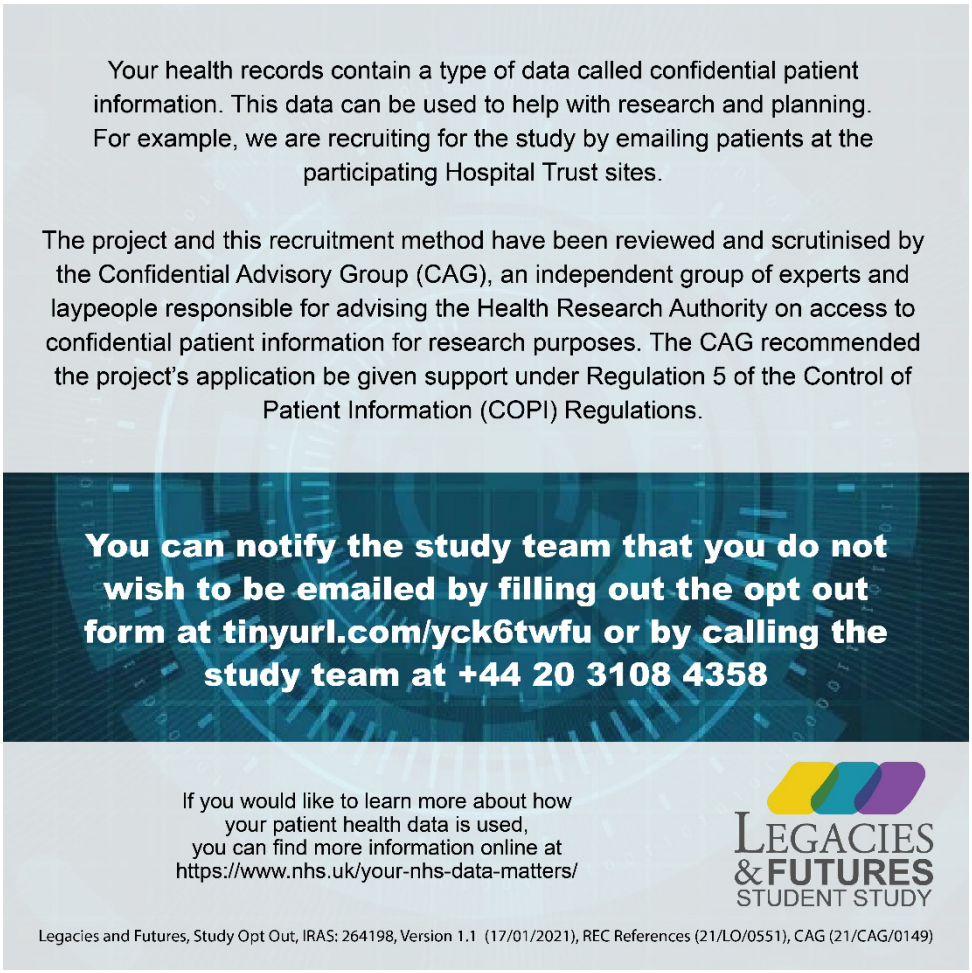
L+F Instagram 2 v1-2.jpg

L+F Instagram 3 v1-2.jpg

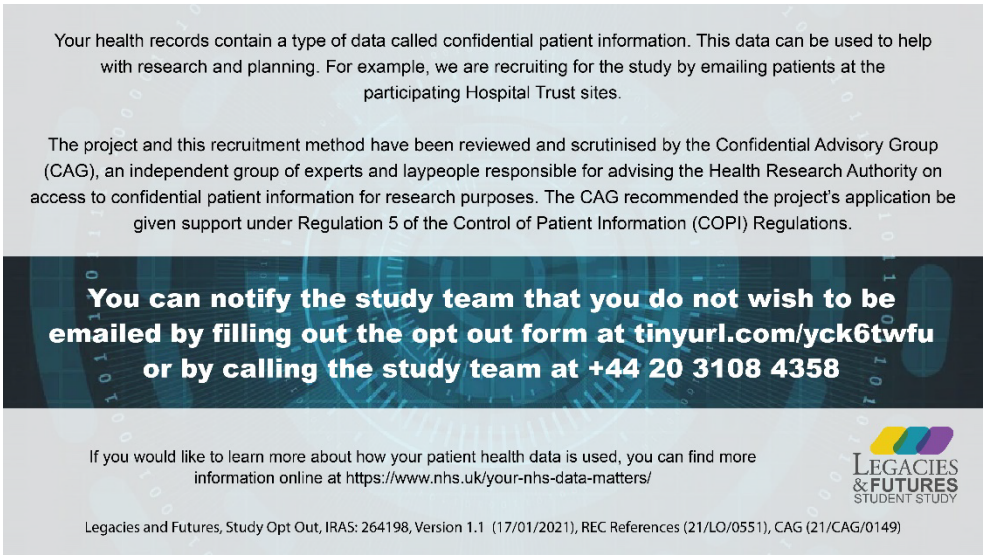
10.4.2.2.5 Notification of CAG approval and opt out process



Study_Opt-Out_V1-1_Facebook.jpg



Study_Opt-Out_V1-1_Instagram.jpg



Study_Opt-Out_V1-1_Twitter.jpg

10.5 Participation Compensation

Funding have been received from the Society for the Psychological Study of Social Issues to cover the compensation of participants that are taking part in the sub-study (section 13). Participants will not be made aware of this compensation until after they have completed the activities.

11 CONSENT

There are multiple steps in this study which will include phasing both prior to and after participant consent has been given. Appendix 12 provides a copy of the study consent form.

11.1 Activities Prior to Participant Consent

As part of the recruitment process, to be discussed next, there will be the need to contact current antenatal patients using their listed email addresses. Because this would take place prior to consent, the process will be conducted under Section 251 of the National Health Service Act 2006, which allows for access to patient data without consent for recruitment purposes. More detail is provided under section 8.1 of the protocol, including dissent and the reduction of contacting patients prior to their consent.

11.2 Participant Consenting Process

Consent will be gathered through Research Electronic Data Capture (REDCap), a survey platform that is integrated into secure systems, hosted on the UCL Data Safe Haven. Collection of consent through electronic means has a supported precedence in medical studies in the United Kingdom[40] and abroad. Individuals interested in participating will be asked to consent to their participation in the study when they access a link to the REDCap survey. Using branching or digital skip logic, which limits the ability of user to proceed through a survey, the survey will require participants to acknowledge they have read the patient information sheet and are aware of what study activities they are consenting to through completing the form. This will allow for digital records of consent, with electronic time stamps, to be kept securely on the Data Safe Haven and to be archived separately from the study data upon completion. Besides checking boxes in agreement, participants will also type out their name and provide an electronic signature. Additionally, a copy of the participant's consent form will be immediately emailed to them for their records, so that they are able to refer back to the form if needed. More information on both REDCap and the Data Safe Haven is available in appendices 13 and 14, and are discussed within the data management plan below.

11.3 Time Limitations for Consent/Dissent

With the survey available online, the only potential limit to time for deciding is the length of their pregnancy. If participants have given consent and chose to no longer to participant and/or grant access, they can leave the study prior to any identifiable information being removed from the dataset (also called data pseudonymisation), with confirmation that their data will not be included within the dataset for final analysis.

12 METHODS AND DATA SOURCES

12.1 Methods Summary

- Quantitative Data Collection
    - Two online panel surveys
        - once during pregnancy and once postpartum
        - 30-45 minutes to complete each survey
    - Electronic Health Records
- Qualitative Data Collection (ULCH only)
    - At-home Journal Activity (details in Section 13)
        - Approximately 2 hours effort
        - Completed between survey 1 and survey 2 (with some overlap)
            - a submission reminder is sent with survey 2

12.2 Sources of Survey Measures

In order to build the survey, existing measures were used. The questions within the survey measures have been chosen based on their development in either LGBTQIA+ research and/or perinatal research, with special interest in measures that were created using patient involvement. For example, the MADM scale was developed using participatory methods with pregnant patients while the patient experience scale was validated in a sample with both LGBTQIA+ and cisgender heterosexual parents.

12.3 Quantitative Data Collection

There are two sources of quantitative data: primary survey data and data from patient records. The online surveys will be used to collect psychosocial data and more detailed demographic data. The second source of data comes from participant's antenatal tests and appointments, along with postnatal data for both parent and infant, both taken from patient records.

12.3.1 Patient Records

The following information collected directly from patient records is being accessed by the study team to diminish stress caused by the study, to ensure clinical consistency, and to reduce recall bias. Data entered by clinical staff into patient records as part of routine antenatal care is then transferred by the study team and paired with the panel survey responses in a secure database via REDCap. Participants will be informed which data from their records will be used by the researchers and provide their consent before any of the information detailed below is accessed for use in the study. No patient health data will be accessed or used without prior consent.

12.3.1.1 *Pregnancy Outcomes and Neonatal Health*

While documenting birth outcomes and neonatal health, there are a standard set of measures taken right after birth to track growth and development from infancy. These include length/height, weight, head circumference, length of pregnancy (i.e., gestational length), and Apgar score. The latter measure, which is the most complex indicator, is a five domain score that monitors 1) breathing effort, 2) heart rate, 3) muscle tone, 4) reflexes, and 5) skin colour.[41] Each domain can have a value

of 0-2, with an ideal score of 10, with assessment done at 1-minute post birth and 5-minutes post-birth. When additional monitoring is necessary, clinical staff does a third assessment at 10-minutes. Use of standard clinical measures for assessing infant health as indicators for overall outcome follows the efforts to reduce the study's impact while allowing repeatability in a standard clinical setting. With complications during the pregnancy and/or birth, these elements will also come from the patient health records.

12.3.1.2 *Demographic Data*

To reduce the time and stress placed upon participants, we will draw certain demographic data from patient records rather than asking them to complete additional questions in the survey. Patient age and residential post code will be extracted; with ethnicity both asked and extracted. Post code will be used to determine each participant's "deprivation score"; a composite score that looks at the health of localised areas across England, using weighted scores for the domains, broken-down in Table 1. The deprivation score will serve as an indicator of vulnerability (included as a structural stressor in Table 3 on page 30), as it represents a community-level measure of resources.[42]

Table 1: Deprivation Score Domains

Domain	Weight
Income	22.5%
Employment	22.5%
Health & Disability	13.5%
Education, Skills, & Training	13.5%
Crime	9.3%
Barriers to Housing & Services	9.3%
Living Environment	9.3%

12.3.1.3 *Allostatic Load*

As there is presently no gold standard for measuring and scoring allostatic load in pregnancy,[43,44] the proposed analysis (see page 29) takes into consideration the routine clinical tests in antenatal care along with guidance on expanding biomarkers to be more inclusive for racial and ethnic minorities.[45–47] In order to measure allostatic load (as shown in Table 2), data from four biosystems will assess for overall dysregulation: 1) the cardiovascular system, 2) the metabolic system, 3) the inflammatory system, and 4) the neuroendocrine system. Natural variability within each of the four systems is present as part of foetal development.[48] For analysis, primary indicators for cardiovascular, metabolic, and inflammatory systems, averaged to address the regulatory fluctuations of biosystems within each trimester, will make up the allostatic load index.[48] Including variations in care and site guidelines because of COVID-19.[49–51] Biomarkers and proxy values are extracted from participant's antenatal records to build a model of allostatic load throughout pregnancy.

12.3.2 Longitudinal Panel Survey

Using existing, validated scales, identical panel surveys will assess for differences in resilience and vulnerability scores in pregnancy (survey 1) and postpartum (survey 2). The Research Electronic Data Capture (REDCap) survey platform (see appendix 13) will collect data securely, allowing survey responses to be stored directly onto a digitally secure remote server that will be accessed by the study team (i.e., the Data Safe Haven—see appendix 14). Data extracted from patient records will be linked to participants survey responses after participation via data entry forms in the secure REDCap platform.

12.3.2.1 *Allostatic Load*

The Edinburgh Postnatal Depression Scale (EPDS) is part of the longitudinal panel surveys, as mentioned in Table 2. This scale, developed and validated (α=0.87) in Scotland, is widely used in the UK with parents during pregnancy and postpartum.[52]

Table 2: Parent Allostatic Load Biomarkers and Proxies

Biosystem	Antenatal Test	Collection Points
Cardiovascular system	Systolic blood pressure	All routine appointments* • *Initial appointment* • *At 16 weeks* • *By 22 weeks* • *At 28 weeks* • *At 34 weeks* • *At 36 weeks* • *At 38 weeks* • *By 41 weeks*
	Diastolic blood pressure	All routine appointments*
Metabolic system	Body mass index	Pre-pregnancy By 41 Weeks
	Glycated haemoglobin	First trimester Second trimester* Third trimester
	Urinalysis (dip and/or microscopy)	All routine appointments*
Inflammatory system	White blood cells count	First trimester Second trimester* Third trimester
Neuroendocrine system	Edinburgh Postnatal Depression Scale (EPDS)	Panel Survey 1 Panel Survey 2
	Fundal height	All routine appointments*

*when available because of COVID-19 guidance and potential differences in site implementation

12.3.2.2 *Vulnerability: Measures*

Scales used to assess vulnerabilities are listed in Table 3, and the details of the variables (grouped by indicator and/or construct) are laid out in appendix 15. The included scales were selected because of their ability to measure both proximal (intrapersonal) and distal (interpersonal) minority stressors, along with more general measures of stress (e.g., household and community level resources) to allow for the additive nature of minority stress to be assessed. Most of the scales were validated in LGBTQIA+ led and focused projects, which was a point of importance in the development of this study.

Table 3: Sources for the Vulnerability Indicators

Scale	Source of Variables and Methods	Latent Variable
Level of Outness*	Meyer, Rossano, Ellis, & Bradford[53]	Intrapersonal stressor
Felt Stigma	Herek, GM[54]	Intrapersonal stressor
Homelessness/Child Welfare	Harris & Udry[55], adapted by Meyer, et al.[56]	Interpersonal stressor
Police Interactions*	English, Bowleg, Rio-Gonzalez, Tschann, Angans, & Malebranche[57], amended by Meyer, et al.[56]	Interpersonal stressor
Stressful Life Events	National Institutes of Health[58]	Interpersonal stressor
Everyday Discrimination	Williams, Yu, Jackson, & Anderson[59], adapted by Meyer, et al.[56]	Interpersonal stressor
Chronic Strains	Wheaton[60], abridged by Meyer, et al.[56]	Interpersonal stressor
Household Vulnerability Index*	Flanagan, Gregory, Hallisey, Heitgerd, & Lewis[61]	Structural stressor
Deprivation Score	Ministry of Housing, Communities, & Local Government[42]	Structural stressor

*Adapted or further adapted for this study

Table 4: Sources for Resilience Indicators

Scale		Latent Variable
Coping*	Carver, Weintraub, & Scheier[62], Carver[63]	Intrapersonal resilience
Perceived Social Support	Zimet, Dahlem, Zimet, & Farley[64]	Intrapersonal resilience
Patient Experience Scales* (comfort, trust, safety, support)	Luxion[7]	Interpersonal resilience
Shared Decision-making (competence, control, communication)	Vedam, Stoll, Martin, Rubashkin, Partridge, Thordarson, & Jolicoeur[65]	Interpersonal resilience
Emotional Reactivity	Jimenez-Torres, et al.[66]	Interpersonal resilience
Community Connectedness*	Frost & Meyer[67]	Sociopolitical resilience
Civic engagement	Porter[68] & Pancer,[69] adapted by Meyer, et al.[56]	Sociopolitical resilience

*Adapted or further adapted for this study

12.3.2.3 *Resilience: Measures*

Scales used to assess resilience are predominantly from ante- and perinatal research studies. An exception to this is the emotional reactivity scale, which was validated in HIV+ Latin women.[66] The only scale validated in a study on LGBTQIA+ pregnancy is the Patient Experience scale.[7] Along with the further details in Table 4, these measures are laid out in appendix 15.

12.4 Inclusion of Neonate Patient Data

Data on infant(s) health in the neonatal period, immediately following birth, will be obtained from electronic medical records. This is to allow access to birth outcomes data.

Gestational patients who are taking part in the study, who were recruited during their pregnancy, will be asked to provide the details necessary to link infant patient records with their parent's survey responses. The consenting process of the gestational patient will include that this need for and use of foetal and infant health data will be part of the collection process. The consenting processes and patient information sheets will be given only to the gestational patients who are taking part in the study. As the neonates would be too young to give consent and the consent necessary is only to health records and not for any care, clinical visits, or any other face-to-face activities, the study requires only the access to information request and consent from the parents.

13 Qualitative Sub-study

Materials for the sub-study and directions for the participants can be found in the appendices of this protocol (20a and 20b). The following sections are focused on the details of the sub-study.

13.1 Subsample

A nested subsample will be selected from the survey participants that are receiving antenatal care at University College London Hospital (UCLH) to take part in a set of at-home journal activities. Comprising 30 participants, the nested sample will be broken-down into three groups: 1) cisheterosexual parents (n=10), 2) LGB+ cisgender parents (n=10), and 3) transgender parents (n=10). UCLH study participants can opt-in to the sub-sample while completing the first panel survey, using the journal activity screening questions provided (appendix 16). Participants from UCLH will be asked in the first panel survey if they have interest in participating in the qualitative sub study and completing journal activities. The survey responses of those participants indicating interest will be examined to guide purposive sampling (i.e., non-homogeneity of vulnerability and resilience scores). Selecting a balance of the higher and lower scores follows an extreme-case approach as an means of integrating qualitative and quantitative data.[70]

Table 5: Qualitative Sampling Approach

	Cishetero.	Cis-LGB+	Trans*
High Res./Low Vul.	5	5	5
High Vul./Low Res.	5	5	5

13.2 Recruitment

Participants who are taking part in the study at UCLH will be asked at the end of their first survey if they would be interested in participating in the qualitative sub-study.

After completing the first survey, the resilience and vulnerability psychometric scales will be scored through calculated variables on REDCap (appendix 16). These scores will give an idea of which participants meet the extreme-case criteria discussed in section 13.1 above. If a participant is interested in the sub-study, their resilience and vulnerability levels as composite scores will be reviewed and compared. What is being review is whether at least one of their composite scores is

either extremely high or low in comparison with the other score. For example, a participant with middling values for both scores would not be eligible, while a participant with extremely high resilience and extremely low vulnerability would be an ideal candidate.

13.3 Consent

Before participating in the qualitative sub-study, interested participants will have to complete an additional consent form (appendix 17) that will be completed prior to receiving the journal activities below, after reading the sub-study PIS (appendix 18). This will follow the same approach as the main study, with an electronic consent form that is kept separate from the participants record with a copy immediately emailed to the participant for their records.

13.4 Qualitative Data Collection

At the end of the first panel survey, participants at University College London Hospital (UCLH) will be asked if they are interested in completing an at-home journal activity before being screened and assessed for their eligibility (see Table 1 on page 21). When eligible, they will be asked about their preferred methods of completing the journal activities (appendix 19). Participants can choose from two completion and submission processes as part of this form: 1) the digital packet to be uploaded or mailed-in when complete with postage paid (appendix 20a) or 2) a hard copy A5 journal (appendix 20b), to be mailed to the participant, with submission directions and/or a postage paid return envelope. Multiple options have been made available to allow for variations in participants' level of digital literacies.

13.5 Journal Activities

To aid participants with writing in their journals, whether hard copy (appendix 20a) or digital (appendix 20b), there are three prompts as mapping exercises included within the journal. These prompts are included along with directions for the journal activities, which clarify to participants that there is no wrong way to use the mapping prompts and no wrong way to complete the journal activity.

The prompts, in the form of maps, will serve as a tool to help participants determine what they want to include within the journals rather than as a source of data. Though they may help connect the quantitative and qualitative data chronologically. The first journal map has prompts that focus on events during pregnancy, broken down into four sections: pre-conception, first trimester, second trimester, and third trimester. The second map's prompts focus on events during labour and delivery, including right after the birth as: early labour, active labour, birth, recovery. While the third map's prompts focus on the first month postpartum, inclusive of the first infant check-up, along with the participant's own recovery and adjustment period.

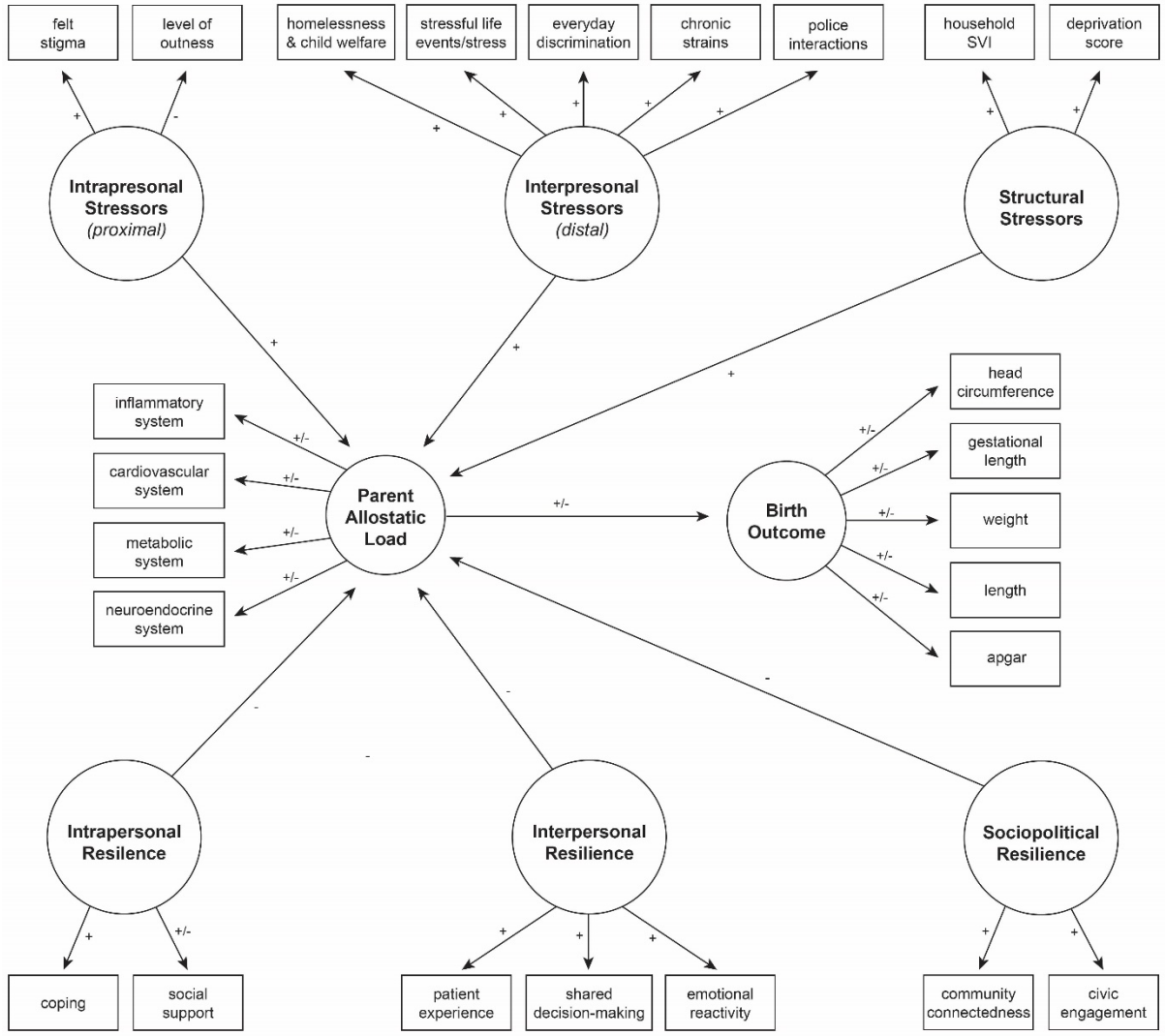
This at-home journal activity is expected to take no longer than two hours to complete with no expectation for what the participants will include beyond the pregnancy and childbirth themes mentioned by the mapping prompts. This time estimate is assuming that participants my take up to an hour to write about their experiences while pregnant, and up to another hour to write about their experiences after giving birth or experiencing a loss, and any experiences postpartum they feel are relevant. This estimate of two hours is the equivalent amount of time that would be scheduled if an interview were conducted at each of these time points. However, with the journal activities, participants will be able to instead work at their own pace, write privately, and be able to complete the activity in a safe space. As the activity is not being timed and will vary between participants, it could also take as little as 30 minutes to complete the activity in its entirety. When complete, participants will confirm completion and submit their journals via a submission form (appendix 21).

14 QUALITATIVE AND QUANTITATIVE ANALYSIS

14.1 Structural Equation Modelling

Using the free data analysis software R and the lavaan package, the quantitative data will be analysed using longitudinal Structural Equation Modelling (SEM). This combines the panel survey data and patient record data within a test of a hypothesized model (Figure 4). This statistical method will allow for the hypothesized roles of resilience and vulnerability to be tested through using the questions that are being asked in the survey instruments. When it is not possible to directly observe concept, latent (i.e., unobservable) variables can become measurable by recording observable components of those concepts. For this study, the observable variables, discussed in the survey instruments sections, define resilience and vulnerability and how these concepts link into the health of the gestational patient, and how they also link into their pregnancy and birth outcomes. These variables are laid out visually in Figure 4 on page 34. The fit of the model will be compared between LGBTQIA+ participants and cisgender heterosexual participants in order to examine inequality in health and their explanatory processes across the two subsamples.

Figure 4 - Hypothesised Structural Equation Model (simplified)



14.2 Narrative Analysis

The qualitative data collected through the journal activities will be analysed using narrative analysis, following the key themes and events that the participants have chronicled during their pregnancy and within the month after birth. Narrative analysis is a grouping of methods that are used for the analysis of texts, specifically as a method of organising meaning and providing chronological structure to events and human actions from parts into a whole.[71,72] Narrative analysis allows for the review of participant's experiences and navigation throughout antenatal care, childbirth, and postpartum, making the most out of the study's methods.

Providing explanations and explorations in the narratives of LGBTQIA+ pregnancy and parenthood will enable a dialectical approach to data integration within the analysis (discussed on page 32) while also being able to account for additional points of concern and minority stressors (e.g., fear of childbirth),[10,73] and to allow for further discussion of resilience responses.

Once the journals are received from participants, depending on if they are hand written or typed, the information will be input into NVivo on the Data Safe Haven to be transcribed and notated, as necessary. After the initial process of establishing the themes, responses will be organised into chronological narrative arcs, with the themes noted.

14.3 Integration of study and sub-study data

The data from the study and sub-study are being collected in a way to allow for them to work together in the analysis process. This is being done by allowing the data to "speak to each other" as a way to better understand the bigger picture.[74] With two survey points and a sub-study with a journal activity in-between, this allows for both the qualitative data and quantitative to have a narrative arc, which means that resilience and vulnerability elements can be mapped with medical data to deepen what is observed in the participants' experiences.[75,76]

15 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCL Research Office and deemed sufficient to cover the required the study activities, as the PhD student will be responsible for the majority of the study tasks. NHS costs have been projected as zero per site because of the PhD student providing the efforts necessary for the project, with site support available through the Local Clinical Research Network when the site already has support in-place. There are no care costs or changes in procedure to incur further cost associated with this study. This has been discussed with each study site during the planning process. The project is being sponsored through a doctoral studentship that is overseen by the UBEL Doctoral Training Partnership with funding provided by the ESRC (Grant Reference: ES/P000592/1).

The funds that are covered through the Doctoral Training Partnership include tuition for the PhD Student and annual maintenance, with a London allowance. At present, there is no further funding available or necessary for the study to take place.

15.1 Conflict of Interest Statement

There are no conflicts of interest for the CI of the project or any other investigator/collaborator. This means that there is not any direct personal involvement (e.g. financial, shareholding, personal relationship, etc.) in the organisations sponsoring or funding the research that may give rise to a potential conflict of interest.

16 DATA HANDLING AND MANAGEMENT

The study complies 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 General Data Protection Regulation (2016/679) regarding the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer can be reached through data-protection@ucl.ac.uk. As this is a student project, the data processors for the data from all four sites are Kate Luxion (PhD Student), David Frost (CI/PhD Supervisor), and S. Melissa Whitten (Co-Supervisor). Figure 1 explains the flow of information from each site to the study team, who will use the Data Safe Haven to complete all the steps for the project to be completed securely.

The study will collect the personal data laid out in the attached survey measures as they are necessary for the assembly of the vulnerability and resilience constructs. Examples of the personal data to be collected directly from the participant through the study measures are:

- Name
- Hospital ID no.
- Date of Birth (used for age and linkage)
- Email address (used for recruitment and linkage)
- Gender
- Sexual Orientation
- Partnership status
- Education Level
- Employment Status
- Boroughs for living and working (depreciation score)
- Mode of transportation
- Ethnicity

Patient data that will be extracted from the electronic health records includes:

- Gestational patient: Blood Pressure
- Gestational patient: Urinalysis
- Gestational patient: Height
- Gestational patient: Weight
- Gestational patient: BMI
- Gestational patient: Routine blood draw (i.e., white blood count, etc.)
- Gestational patient: Fundal Height
- Gestational patient: Additional measures as relevant (as covariates/control variables)
    - Pre-existing conditions (i.e., PCOS, diabetes, etc.)
    - Any further antenatal tests (as requested by care team)
    - Details on birth (i.e., length of labour, interventions, etc.)
    - Complications for parent (i.e., maternal mortality, length of hospital stay, etc.)
    - Any further tests requested by care team related to pregnancy/labour/recovery
- Infant: APGAR Score
- Infant: Gestation length
- Infant: Birth Weight
- Infant: Height/length
- Infant: Head circumference
- Infant: Additional measures as relevant (as covariates/control variables)
    - Complications (i.e., further monitoring, need for time in NICU, miscarriage/stillbirth/infant mortality, etc.)
    - Care processes (i.e., skin-to-skin time, supplementation, etc.)
    - Any further tests requested by the care team related to infant health

Data transfer between the hospital sites and the data processors will take place over the secure network provided by the Data Safe Haven, hosted by UCL. The Data Safe Haven is a remote server that uses a wall-garden approach to allow for the securing of identifiable data in a way that meets NHS standards. This is done through a two-factor security approach that relies on both a password and a fluctuating key fob that cycles through the secondary authentication code. The core research team (PhD student, CI/Primary supervisor, and Co-supervisor) will be the only members with direct access to the data, which is a limit placed to ensure patient-participant confidentially across a multi-site project. The Data Safe Haven also provides a secure storage method - both within the timeline of the study and in compliance with the necessary archival of the data associated with the project. Data collection through REDCap on the Data Safe Haven keeps the assurances laid out in appendix 15, as it cordons off the survey responses directly to the 1 terabyte server space set aside for the Data Safe Haven project that is registered with IT at SLMS at UCL.

All personal, identifiable data will be kept separate from the data that will be analysed in order to protect the safety and security of their identity and information. Records will be linked using a randomly generated participant identification number. Only the PhD student will have access to the dataset that has the identifiable data in order to ensure responses are linked correctly. This will allow for a de-identified dataset during the analysis process. Upon completion of the study the anonymised data will be archived on the Data Safe Haven. Personal data, without permission to contact for future research, will be stored or accessed less than 3 months after the study has ended.

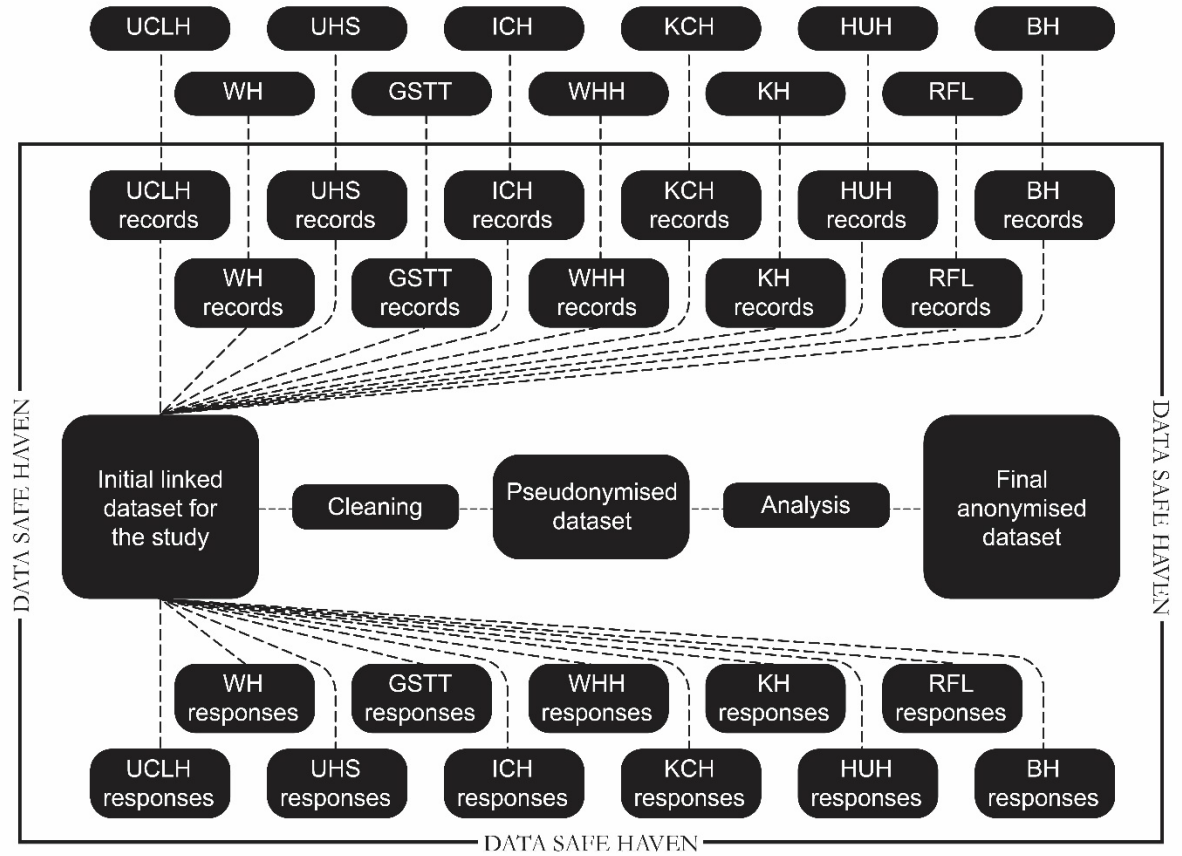


Figure 4 - Flow of data from sites to Data Safe Haven

16.1 Data Safety and Monitoring

Mx. Luxion, as the PhD student, will serve as the asset manager for the data housed on the Data Safe Haven. Dr Frost, as CI, is listed as the asset owner and will maintain oversight of Mx. Luxion. A platform available through UCL, the Data Safe Haven has been developed to provide a secure area

for data collections that involve identifiable data, including data collection, data storage, and data analysis, with the latter possible because of software integrated into the Data Safe Haven.

When it is necessary to transfer data from sites to UCL, it will be done securely using the transfer links available through the Data Safe Haven. This will allow for a completely secure transfer from NHS computers directly to the Data Safe Haven, ensuring that the entire data management process meets the required standards of patient data per the NHS and GDPR. There will be no transfer of identifiable data between sites, data will only go from the hospital sites to the research team via secure links to the Data Safe Haven.

16.2 Sensitive Data and Confidential Advisory Group Review

Because of the methods needed to recruit patients, there is advice being using the contact information that is available in their health records, this project is seeking permission to access this information prior to receiving consent. There will also be confidential and sensitive information that is being requested about biomedical tests that are standard within antenatal care which comprise the variables in the analysis. Aside from contact information and antenatal test results, the rest of the patient information being requested deals with data variables and the ability to link responses to patient records with accuracy.

The identifiers that we will request access to will be for either the purposes of linking patient records and survey responses, or for model building and data analysis. For the linkage of patient records and survey responses, we will need:

- Name (Patient Records)
    - To ensure that the right patient record has been located properly for linking
- Hospital ID no. (Patient Records)
    - For locating and linking infant health records
- Date of Birth (Survey)
    - Used to calculate age, risk, assessing eligibility for study, linking to patient records
- Date of Death (Patient Records)
    - To assess for maternal mortality within the samples
- Geographic identifiers (Survey)
    - The post code for the live and work boroughs collected will be used for assigning the deprivation index value as a structural indicator of vulnerability.

In order to develop the SEM for data analysis, the following identifiers are necessary:

- Date of Birth (parent, Survey)
    - Used for calculating age
- Date of Birth (infant, Patient Records)
    - Used for calculating gestational length
- Date of Death (parent and infant; Patient Records)
    - To assess for infant and parent/maternal mortality within the samples
- Gender (Survey)
    - This is special category data that is necessary because of irregularity in collecting gender as a non-binary variable in-clinic and being a key variable in the research objectives
- Sexual Orientation (Survey)
    - Another variable that is necessary to fulfil the key research objectives
- Ethnicity (Patient Records)
    - Necessary to fulfil the key research objectives to assess for minority stress

These sensitive data that will be collected, as mentioned above, will be gathered from electronic health records from the gestational patients and their neonates, along with the two surveys and the journal activity. The survey data is gathered online, using REDCAP, while the journal activities are to be completed in a booklet at home. Data from the electronic patient health records will be extracted once per month in order to recruit and build out the sample. For analysis, the variables will go into calculating an allostatic load, which is a score for health and wellbeing. Additional variables are addressed earlier in section 12, this includes both antenatal and postnatal parent data, and requesting access to foetal and neonate health data.

The justification for access to this data is that access to medical records is imperative for this study to succeed. The decision to take this approach was reached in consultation with the clinical staff who serve the patient populations at the centre of this study. In order to link the patient records and data sets, it is necessary to have access to patient identifiable data until the point of analysis. Using factual identifiers is necessary for having at least two points of comparison to make sure that the responses and patient records are properly matched, particularly if respondents register in the study with an email address different from the recruitment email address.

16.2.1 Classes of Section 251 Support

The following classes apply to this project:

- Class 2 Support: to obtain and use information about past or present geographical location
- Class 3 Support: to select and contact patients to seek their consent
- Class 6 Support: to allow access to an authorised user for one or more of the above purposes

16.2.2 Compliance with GDPR and Data Protection Act 2018

16.2.2.1 Fair Processing

As part of the methods, it is planned to have as many elements of the project open access when ethically possible. This includes transparency of data analysis steps that take place in this project, all of which will be recorded within the methodologies section of the resulting PhD thesis. As an academic research project, the tasks involved are in the public interest in the form research and archiving. In this way, the study will benefit the health of a key under-represented group through leading to better policy because of the research activities.

Under GDPR, these activities fall under lawful use because of their use for "public task" and "research purposes", with the latter covering the use of special category data and both enabling use of personal data. The methods chosen have been done so to reduce the amount of data necessary, and the amount of people accessing the data - something that is noted in the PIS as part of the transparency protocol. Another means of reducing the impact on individuals through this processing method is to give them a space where they can disclose their gender identity and sexual orientation without having to disclose this information to their clinical care team. In this same vein, we are also sharing the approved methods and updates to be as transparent as we can about the project details, while maintaining the security of the participants' data. This is how we are ensuring "fair processing" within the project, as an extension of transparency, all of which is noted in the PIS.

16.2.2.2 Minimum necessary for the purpose

Prior to consent, the data that is being accessed is for recruitment and thus limited to eligibility criteria and contact information. Any additional access will be done after consent has been granted to ensure the minimal amount of processing necessary to allow for the project to remain possible.

16.2.2.3 Accuracy

All steps of this project will be recorded in research logs for the funder and for review with the project CI/primary supervisor, secondary supervisor, and PhD student. Part of this process will include use of a syntax record (which is a step-by-step record of the process) for data analysis.

16.2.2.4 Kept for minimum time necessary

Using identifiers to link the accounts (i.e., name, hospital ID, etc.) will be used only for the length of necessary, which will vary based on length of pregnancy and recovery period post-birth (maximum of 10 months). Once responses are linked, the data set used for analysis will be first pseudonymised and then anonymised per the flowchart included in the Data Management section of the protocol.

16.2.2.5 In accordance with rights of data subject

Consented data will be subject to research, so all participants will be asked for consent to use their patient records as part of the informed consent process after recruitment. No data will be used without consent of the patient-participant outside recruitment.

Approaching the pseudonymisation and anonymisation as described in #5 should improve the ability to remove participant data if they revoke their consent during the study. While it may remain difficult, it is the priority of the study team to put in place security through the Data Safe Haven to allow for more participant control around the use of their data even after consent.

16.2.2.6 Security and confidentiality protection

The Data Safe Haven is remote walled-garden hosted at a physically secure data centre. To ensure continuous security, the Data Safe Haven is subject to rigorous audit procedures besides being physically secure. For access, the Data Safe Haven uses a dual-factor authentication that requires a password along with a physical key that is provided through smartphone app. Personnel able to access the unique SharePoint for the project are restricted to the CI/primary supervisor, secondary supervisor, and PhD student. All data collection and analysis will take place on this SharePoint as well to ensure the patient data never leaves a secure space physically or digitally.

16.2.2.7 Not disclosed outside the EU

No personal identifiers will be shared outside of the EU, or outside of the project team.

16.2.2.8 GDPR Principle (b)

The study team has gone through steps to particularize the purposes for the processing of the data prior to consent, which are documented within this application. As mentioned in the application, there will be ongoing review of these processes with updates to the documentation as we try to move away from using data without consent. This will also allow for the meeting of all tenets in purpose limitations as the ongoing review will make sure that the purposes are maintained and not repurposed needlessly or without further oversight, regardless of there being no intention to have a new purpose for access to contact and patient details prior to consent.

16.2.2.9 Accountability

In order to address the principle of accountability within GDPR requirements, this project has paid special attention to the details of interacting with the data safely and securely. This includes the access of data prior to consent. Through the Data Safe Haven and remote access to the patient health records, the study team has chosen an approach that will allow for the data to be processed without leaving a protected network. The process uses technology that requires GDPR compliance for continued use. This includes ongoing training in GDPR compliance and ongoing training in NHS data security. The processing steps have been laid out in the CAG application and within the study protocol. As part of the recording of contact, consent, dissent, and data processing, there will be a record of the processing activities to allow for review and assurance that the proper procedures are

taking place. This also includes limiting the access of the data through the Data Safe Haven, having the CI serve as the information asset owner and the PhD student researcher serving as the information asset manager, as both roles require detailed record keeping, the ongoing training mentioned above, and is part of a scheme that audits the project-based users to make sure that they strictly comply with relevant GDPR and Data security regulations (i.e., the 2018 Data Protection Act).

16.2.3 NHS Information Governance Toolkit

UCLH has undertaken a self-assessment annually, with the most current overall score being satisfactory at 83%. An exception is 2010-2011, where the self-assessment was Not Satisfactory. UCLH has been granted a satisfactory grade through the Information Governance Toolkit. A data protection impact assessment has been completed for the project and will be registered with UCL. Through the Data Safe Haven set-up, all potential working sites, on-campus or in private home offices, will be review and include a self-assessment related to the safety of the data.

16.3 Information Security Measures

The project development has paid close attention to the safety and security of the data that will be collected, accessed, and analysed, and the health and well-being of the participants. Mx. Kate Luxion will also serve as the information asset manager for the Data Safe Haven at UCL under the supervision of Dr David Frost as the CI and information asset owner. This is of note as this guarantees a consistent upkeep of data security standards training.

16.3.1 Security and Audit Measures

Data will be stored and processed in the SLMS Data Safe Haven, which is a safe haven system.

Access is via a remote desktop arrangement served via Citrix. Access is controlled via the use of a username, password, PIN and one-time token-based password. The token-based password is generated algorithmically and is changed every minute.

Customers are supplied with a password generating key fob or smart phone application to generate this. The Data Safe Haven is subject to external professional penetration testing on an ongoing basis. Reports on this are available.

Failed logon attempts are recorded in the Data Safe Haven system and are managed by the Data Safe Haven Service Operation Manager. Intrusion attempts and port scans are detected and reported to the UCL security function for investigation as necessary.

Data is transferred into the system via a secure gateway technology and is then kept via policy and systems that prevent data leakage (for example, through transfer of data to USB media or copy and paste to the client machine).

The SLMS Data Safe Haven is certified to ISO 27001:2013

16.3.2 Organisation's CLSP Compliance

The Data Safe Haven is certified to ISO 27001:2013

UCL has an Information Security Policy, equivalent to a CLSP, which is located here:
https://www.ucl.ac.uk/information-security/information-security-policy

16.3.3 Responsibility for Implementation

Responsibility will fall to the project's CI, David M Frost, Associate Professor of Social Psychology at UCL. He is reachable via his institutional email d.frost@ucl.ac.uk or his office telephone 020 7612 6403.

16.3.4 Organisation's Data Protection Registration

Organisation's Data Protection Registration Number: Z634106

Under the purpose of research, the processing and inclusion of confidential patient information is covered in the classes of data processed by the organisation (UCL) sponsoring the project.

16.3.5 Physical Security Arrangements

Data will be stored and processed in the Data Safe Haven, which is a safe haven system.

Access is via a remote desktop arrangement served via Citrix. Access is controlled via the use of a username, password, PIN and one-time token-based password. The token-based password is generated algorithmically and is changed every minute.

Customers are supplied with a password generating key fob or smart phone application to generate this. The SLMS Data Safe Haven is subject to external professional penetration testing on an ongoing basis. Reports on this are available.

Failed logon attempts are recorded in the SLMS Data Safe Haven system and are managed by the SLMS Data Safe Haven Service Operation Manager. Intrusion attempts and port scans are detected and reported to the UCL Information Security function for investigation as necessary.

Data is transferred into the system via a secure gateway technology and is then kept via policy and systems that prevent data leakage (for example, through transfer of data to USB media or copy and paste to the client machine).

No study data will be transferred outside of UCL or the UK.

16.3.6 Data Linkage and Key

Once the data have been anonymised, the key that links unnecessary identifiers to the dataset will be deleted. The only exception is the participants who consent to being contacted for future research. In that case, the shortened key will still be kept separate from the dataset and stored in a secure location. In all instances access to the key is limited to the CI and the PhD student and will be stored securely on the Data Safe Haven.

17 MATERIAL/SAMPLE STORAGE

There will be no collection or storage of biological materials as part of this study. Any mention of biomedical data is due to it being gathered from patient records once consent is gained. The information collected is addressed in section 12 as Data Handling and Management procedures.

18 ASSESMENT AND MANAGEMENT OF RISK

Potential risks to study participants include the potential negative emotions that can result from answering questions about stress related to discrimination and access to resources. However, this potential risk is judged to be minimal given these are topics people discuss in everyday conversations with co-workers, friends, and family. In order to minimize the potential for negative emotions, participants will be told they can withdraw participation at any time without penalty. There will be a series of resources that will be made available through the PIS and website (e.g., 24-hour help line, NHS services, web resources, etc.) in case there are experiences of negative emotions because of the study materials and/or participation. Additionally, participants are being given instructions and recommendations for maintaining their privacy while completing the study and sub-

study activities as at home. This advice includes remembering that their setting needs to keep in mind who might be able to see their screen, a reminder to delete their browser history, and/or keeping materials password protected (for digital journals) or in a locked space (for hard copy journals).

As debriefing, a thank you page will signpost to these resources at the end of each survey and with the at-home journal activities. Any remaining risks pertaining to security of data storage of personal and sensitive data are mitigated through the secure data handling and management plans outlined above—including not noting patient participation in the study in their health records. Further risks to confidentiality of participation will be mitigated by separating all contact information from participants study data, with linkages made through a randomly generated study ID number. The study data and contact information will be kept in separate locations on the encrypted and secure data safe haven.

18.1 Ethical Considerations

The structure of the proposed research has been developed with considerations for the participants' time and emotional labour undertaken through the data collection process. Upon enrolment in the study, participant will be given details about the study, while informing them they reserve the right to leave the study and request that their information be excluded before participants are given a participant ID. Electronic consent forms will also state that they are granting permission to access patient records without concern for a change in the quality of care or need for additional prenatal health services beyond those recommended by their health care provider(s). Reliance on medical records is to ensure there is limited recall bias, and a reduction in undue stress caused to study participants by asking them to relive clinical experiences. Access to patient records will also ensure that measures will rely on prenatal tests that are taken routinely and with the expressed consent of the patient/participant, not requiring any additional consent or use of NHS resources than necessary. Utilising these sources of data removes the need for additional care or health services to be accessed for the study to be carried out.

18.1.1 Participant Resources in cases of Distress

If participants feel distressed while undertaking the study, organisational resources have been made available to them as part of the PIS (online and in-print) and study activities. A note has been included that these resources are more likely to use language that centres cisgender individuals. These resources include:

The National Childbirth Trust
Website: https://www.nct.org.uk
Support line: 0300 330 0700

Gingerbread: Single parents, equal families
Website: https://www.gingerbread.org.uk
Helpline: 0808 802 0925

Mind
Website: https://www.mind.org.uk
Infoline: 0300 123 3393

Samaritans
Website: http://www.samaritans.org/
Helpline: 08457 90 90 90

Switchboard LGBT+ helpline
Website: https://switchboard.lgbt/
Helpline: 0300 330 0630

18.1.2 Non-notification of Participant's General Practitioners (GPs)

For the safety of the participants, regardless of their gender and sexual orientation, it is not ethical to notify their general practitioner or care team of their participation in the study on their behalf. This is because of the uncertainty in how this disclosure could inadvertently result a change in the quality of their healthcare because of any possible assumptions about their gender or sexual orientation.[77] To be clear, there are no changes in care for the participants of the study, which means that there are no known risks to the study. Because of this, it means that there would be higher risks to participants if their GPs are notified than if they are able to participate in the study confidentially.

18.2 Confidentiality and Data Security

The privacy of the participants will be ensured by both the digital security measures and data analysis procedures. The surveys are online on the REDCap platform on UCL's Data Safe Haven, with the option to upload the at-home journal activities in place of mailing them via Royal Mail. Data storage will then be immediate and within the walled garden security measures of the Data Safe Haven as well. Minimal identifiable information will be needed to link to patient records and confirm the identity while actively contributing data (i.e., Name, DOB, email address, etc.). Regarding special category data (i.e., sexual orientation, gender identity), this will be necessary for the process of analysis, while protected via the Data Safe Haven.

The data will have all direct identifiers not associated with analysis removed through a numerical participant ID. We will construct these new case labels through a key and will eliminate the possibility of duplicate cases over the period of data collection if a subsequent pregnancy takes place. Use of the Data Safe Haven will thus provide a secure platform for data collection, storage, and analysis; with the system tailored to protect identifiable data.

18.3 Potential Risks to the Researchers

Potential risks from the patient population to the researcher may include individuals who are not supportive of the research, feeling the need to contact the researchers either during recruitment or study activities. As for potential risks from the data itself, there will be cases of miscarriage or still births within the sample. Here, there may be mental or emotional stress for the researchers because of this project's topic and data.

19 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

16.1 Definitions of Adverse Events

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved.
Serious Adverse Event (SAE).	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation**, • results in persistent or significant disability or incapacity, or

	• consists of a congenital anomaly or birth defect
*A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.	

19.2 Assessments of Adverse Events

Each adverse event will be assessed for severity, causality, seriousness and expectedness as described below.

19.3 Severity

The categories below are given as an assessment guide for event severity:

Category	Definition
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further procedure; it causes slight discomfort
Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further procedure, but is not damaging to health; it causes moderate discomfort
Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health

19.4 Causality

As there are no changes in care for the study participants, there is not an expected direct result of causality. However, it is the preference of the study team to keep in mind any and all potential outcomes when conducting research.

The assessment of relationship of adverse events to the procedure is a clinical decision based on all available information at the time of the completion of the case report form. If any adverse events occur, the assessment of relationship of an adverse event to this/these additional safety issue(s) will also be carried out as part of the study.

The differentiated causality assessments will be captured in the study specific CRF/AE Log and/or SAE form (amend as required).

The following categories will define the causality of the adverse event:

Category	Definition
Definitely:	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
Probably:	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely
Possibly	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the study procedure). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events).

Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study procedure). There is another reasonable explanation for the event (e.g. the participant's clinical condition).
Not related	There is no evidence of any causal relationship.
Not Assessable	Unable to assess on information available.

19.5 Expectedness

Category	Definition
Expected	An adverse event which is consistent with the information about the procedure listed in the Investigator Brochure, SPC, manual of Operation **or clearly defined in this protocol.**
Unexpected	An adverse event which is not consistent with the information about the procedure listed in the manual of operation **or clearly defined in this protocol.**

* this includes listed events that are more frequently reported or more severe than previously reported

19.6 Recording adverse events

If participants disclose to the study team any adverse events these events will be notated in the participants' CRF. Due to study confidentiality, and patient care being beyond the scope of the CI and the PhD student, no adverse events will be recorded in medical recorded. Instead—and for ethical reasons—the participant will be advised to seem treatment with qualified medical professionals for their own safety and mental health and wellbeing.

19.7 Procedures for recording and reporting Serious Adverse Events

All serious adverse events will be recorded in the CRF and will comply with funder reporting procedures if/when the state of project funding changes.

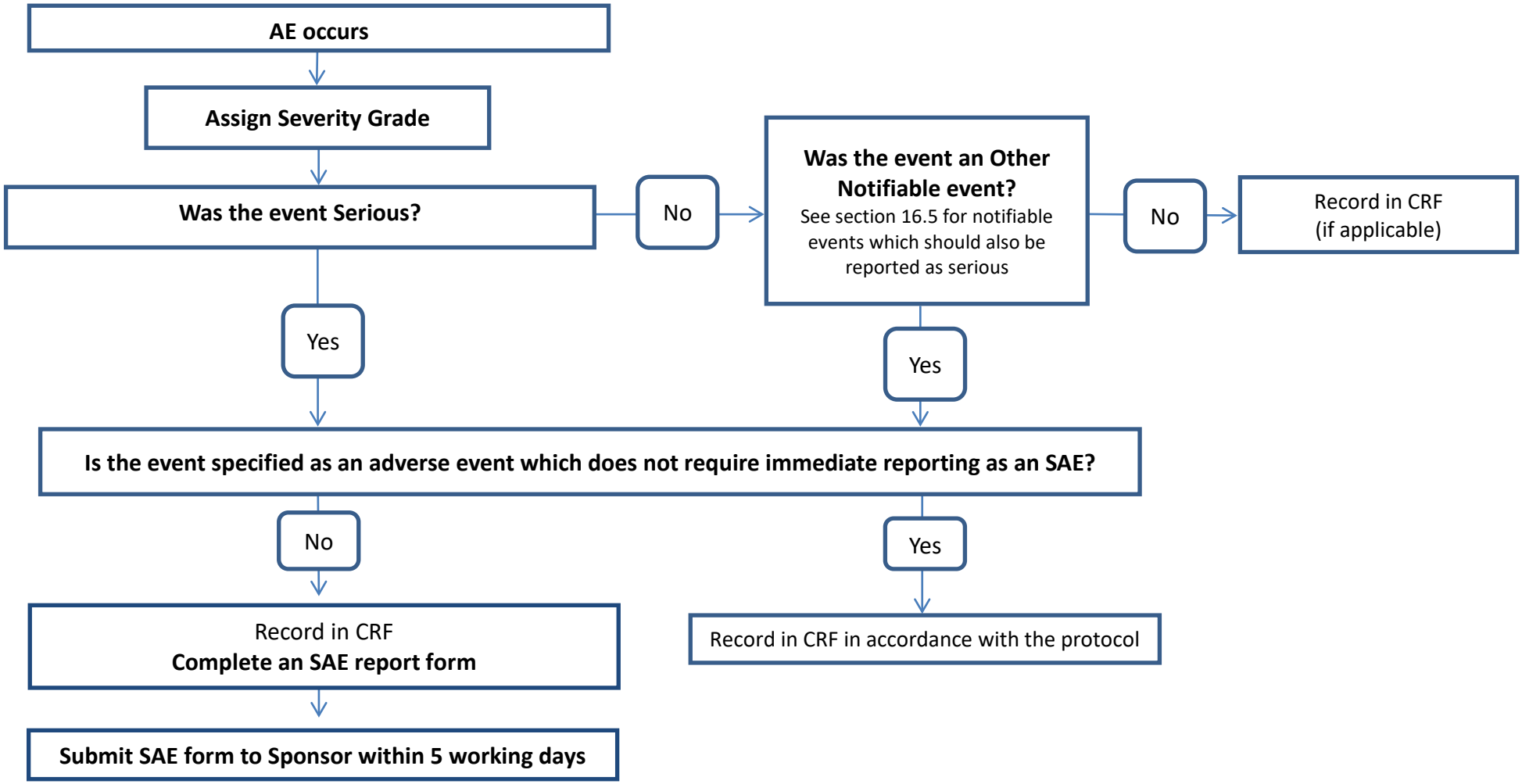
All SAEs (except those specified in section 16.5 as not requiring reporting to the Sponsor) must be recorded on a serious adverse event (SAE) form. The PhD student or designated on-site individual will complete an SAE form and the form will be preferably emailed to the Sponsor within 5 working days (CCing the PhD Student) of becoming aware of the event. The UCL Principal Investigator (the PhD student), under the supervisor of the Chief Investigator, will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the procedure this must be reported by the Investigator to the Health Research Authority within 15 days.

Completed forms for unexpected SAES must be sent within 5 working days of becoming aware of the event to the Sponsor

Email forms to Research-incidents@ucl.ac.uk

Flow Chart for SAE reporting



19.8 Serious Adverse Events that do not require reporting

All SAE will be recorded in order to ascertain the extent of to which the measures and structure of the study design have caused undue stress to participants. Where the safety of the participant is not in question and the concern expressed does not involve a negative impact on their own mental or emotional well-being, the documentation will be treated more as a critique to be kept on record by the study team for future reference.

19.9 Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI/PhD Student shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

19.10 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.

19.11 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.

20 MONITORING AND AUDITING

The PhD student, under the supervision of 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. As this project is an academic endeavour, there will be consistent, ongoing oversight of the project as part of Mx. Luxion's PhD studies at UCL. This oversight is defined as bi-weekly meetings with the primary supervisor (Dr David Frost) and monthly meetings with subsidiary supervisor (Dr Whitten).

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

21 TRAINING

The PhD Student, under the supervision of the Chief Investigator, will review and provide assurances of the training and experience of all staff working on this study. Mx. Luxion will maintain training records in the study files. This training includes, but not limited to:

- Electronic Health Records training
- Yearly GDPR/NHS data awareness training

22 INTELLECTUAL PROPERTY

There is no expected intellectual property generated by this project, since the survey measures are from previous studies. With unforeseen intellectual property, all 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 site taking part, shall belong to UCL. Each site taking part agrees that by giving approval to conduct the study at its respective site, it is also agreeing to assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL, understanding that they may use know-know gained during the study in clinical services and teaching if such use does not result in disclosure of UCL confidential information or infringement of UCL IPR.

23 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 by hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

24 ARCHIVING

UCL and each taking part site recognise that there is an obligation to archive study-related documents at the end of the study (as defined within this protocol). The Chief Investigator confirms that the UCL Principal Investigator will archive the study master file online through the secure Data Safe Haven provided through UCL for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each taking part site agrees to supply the agreed upon data and necessary study documents to be archived securely on the Data Safe Haven as well. As the CI will remain the asset owner through the Data Safe Haven, the project

datasets will remain archived at UCL for up to 5 years after the submission and acceptance of the doctoral thesis. These archival procedures have been determined to ensure they are in line with all relevant storage requirements. During this time, only the personal data of participants who have consented to being contacted for future research shall be kept. This will take place through storing their information in a separate file from the dataset to protect their anonymity in the final versions of the data, while still being able to link their past and future data as needed.

25 PUBLICATION AND DISSEMINATION POLICY

This project facilitates the completion of a PhD in Social Science, with the guaranteed written component being the PhD thesis. There is a plan to publish the findings beyond the PhD thesis, with more details provided through the study website and email list as they become available. For publications external to the PhD thesis, authorship will be determined through consultation by the study team depending on the presentation and/or publication in question. Such publications may also be related to novelties aside from the quantitative and qualitative findings, such as theoretical and/or methodological innovations. The project is funded by the ESRC through the UBEL doctoral studentship, there will be acknowledgements to the funder in all resulting publications.

Information about the study will be found through publication on the HRA website, and through:

- The study website
    - http://www.homepages.ucl.ac.uk/~stnvkll/
- The project page on ResearchGate
    - https://www.researchgate.net/project/Legacies-and-Futures-Gestational-Parents-Experiences-with-Vulnerability-and-Resilience-as-it-Influences-Neonatal-Health
- The study listing on clinical databases once approved
    - Listing on https://bepartofresearch.nihr.ac.uk/
    - ClinicalTrials.gov
    - ISRCTN

The research output may include, among other options:

- Peer reviewed scientific journal paper(s)
- Conference presentation(s)
- Periodic emails to study mailing list
- Updates on ResearchGate, twitter and the study website
- Reports to project funders (UBEL/ESRC and SPSSI)
- A stakeholder meeting at the end of the study

25.1 Identifiable Data

No identifying information will be provided in research outputs. Participant ID numbers will be used for any quotes of qualitative data collected through the journals. The pseudonyms given to participants for their qualitative quotes will not be rooted in their names.

As there are no open-ended questions within the survey measures, direct quotes from the survey are not possible. In the instance where participants use the text fields in a way other than they were intended, a note has been added to the patient information sheet that any information provided to the study (both qualitative and quantitative) may be directly quoted by the study team.

25.2 Authorship

To expand on the topic of authorship around findings, the main output is a PhD thesis. This thesis must be a solo authored document completed by the PhD student, under the supervision of the CI/Primary Supervisor and Subsidiary Supervisor. In the instance of publications beyond this thesis,

the full study findings will be authored by the UCL study team (i.e., Luxion, Frost, and Whitten). Additional publications, particularly those at the site level, should be determined in consultation and collaboration with the UCL study team.

25.3 Informing Participants

At the end of their study activities, participants will be asked if they want to be emailed about research outcomes, including any dissemination of research finding in scientific journals, public-facing reports, lay summaries, and any other approved publication. If they say yes, they will be taken to a separate online form (not linked to the study survey) and asked to provide an email address they would like the information sent to. These email addresses will comprise the study mailing list and it will not be possible to link these email address to study data.

26 REFERENCES

1. Hoffkling A, Obedin-Maliver J, Sevelius J. From erasure to opportunity: a qualitative study of the experiences of transgender men around pregnancy and recommendations for providers. *BMC Pregnancy Childbirth Lond*. 2017;17(Suppl 2). doi:http://dx.doi.org.libproxy.ucl.ac.uk/10.1186/s12884-017-1491-5

2. Röndahl G, Bruhner E, Lindhe J. Heteronormative communication with lesbian families in antenatal care, childbirth and postnatal care. *J Adv Nurs*. 2009;65(11):2337-2344. doi:10.1111/j.1365-2648.2009.05092.x

3. Sbragia JD, Vottero B. Experiences of transgender men in seeking gynecological and reproductive health care: a qualitative systematic review protocol. *JBI Evid Synth*. 2019;17(8):1582. doi:10.11124/JBISRIR-2017-004029

4. Eliason MJ, Chinn PL. *LGBTQ Cultures: What Health Care Professionals Need to Know About Sexual and Gender Diversity*. 3rd ed. Lippincott Williams & Wilkins; 2017.

5. Meyer IH, Frost DM. Minority stress and the health of sexual minorities. In: *Handbook of Psychology and Sexual Orientation*. Oxford University Press; 2013:252-266.

6. Lick DJ, Durso LE, Johnson KL. Minority Stress and Physical Health Among Sexual Minorities. *Perspect Psychol Sci*. 2013;8(5):521-548. doi:10.1177/1745691613497965

7. Luxion K. Serving LGBT+ Parents: How Patient Experiences Influence Birth Outcomes. In: Southeastern Women's Studies Association; 2018.

8. Meyer IH. Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence. *Psychol Bull*. 2003;129(5):674-697. doi:10.1037/0033-2909.129.5.674

9. Ross LE, Siegel A, Dobinson C, Epstein R, Steele LS. "I Don't Want to Turn Totally Invisible": Mental Health, Stressors, and Supports among Bisexual Women during the Perinatal Period. *J GLBT Fam Stud*. 2012;8(2):137-154. doi:10.1080/1550428X.2012.660791

10. Malmquist A, Jonsson L, Wikström J, Nieminen K. Minority stress adds an additional layer to fear of childbirth in lesbian and bisexual women, and transgender people. *Midwifery*. 2019;79:102551. doi:10.1016/j.midw.2019.102551

11. Collins JW, David RJ, Handler A, Wall S, Andes S. Very Low Birthweight in African American Infants: The Role of Maternal Exposure to Interpersonal Racial Discrimination. *Am J Public Health*. 2004;94(12):2132-2138. doi:10.2105/AJPH.94.12.2132

12. Government Equalities Office. *LGBT Action Plan: Improving the Lives of Lesbian, Gay, Bisexual and Transgender People*. Government Equalities Office; 2018.

13. NHS Digital. NHS Maternity Statistics, England 2018-2019. Published 2019. https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2018-19

14. Brighton & Hove City Council. Brighton & Hove City Snapshot: Report of Statistics 2014. Published online 2014:137.

15. Office for National Statistics. Sexual identity, UK. Published 2016. https://www.ons.gov.uk/peoplepopulationandcommunity/culturalidentity/sexuality/bulletins/sexualidentityuk/2016

16. Government Equalities Office. Factsheet: Trans people in the UK. Published online 2018:2.

17. Meyer IH, Wilson PA. Sampling lesbian, gay, and bisexual populations. *J Couns Psychol*. 2009;56(1):23-31. doi:10.1037/a0014587

18. Soper D. A-priori Sample Size Calculator for Structural Equation Models. https://www.danielsoper.com/statcalc/calculator.aspx?id=89

19. Everitt BS, Palmer CR. *Encyclopaedic Companion to Medical Statistics*. John Wiley & Sons; 2011.

20. National Health Services. Choose if data from your health records is shared for research and planning. nhs.uk. Published May 23, 2018. Accessed August 26, 2021. https://www.nhs.uk/your-nhs-data-matters/

21. University College London Hospitals NHS Foundation Trust. Cookies & privacy. Cookies & privacy : University College London Hospitals NHS Foundation Trust. Published nd. Accessed August 25, 2021. https://www.uclh.nhs.uk/cookies-privacy

22. University College London Hospitals NHS Foundation Trust. Protecting patient data in research - security, storage and consent. Protecting patient data in research - security, storage and consent : University College London Hospitals NHS Foundation Trust. Published nd. Accessed August 25, 2021. https://www.uclh.nhs.uk/research/research-and-data/protecting-patient-data-research-security-storage-and-consent

23. Imperial College Healthcare NHS Trust. Imperial College Healthcare NHS Trust Patient Privacy Notice. Published online February 21, 2020. Accessed August 26, 2021. https://www.imperial.nhs.uk/~/media/website/patients-and-visitors/privacy-notice-patients.pdf?la=en

24. Imperial College Healthcare NHS Trust. Patient privacy notice. Imperial College Healthcare NHS Trust | Patient privacy notice. Published April 30, 2021. Accessed August 26, 2021. https://www.imperial.nhs.uk/privacy

25. Harvey A. Your Personal Information (v14.0). Published online April 2021. Accessed August 28, 2021. https://www.uhsussex.nhs.uk/wp-content/uploads/2021/04/Your-personal-information-leaflet-1.pdf

26. Brighton and Sussex University Hospitals NHS Trust. Information we hold about you. Information we hold about you | Brighton and Sussex University Hospitals NHS Trust. Published nd. Accessed August 27, 2021. https://www.bsuh.nhs.uk/your-visit/your-information-and-rights/information-we-hold-about-you/

27. King's College Hospital NHS Foundation Trust. Use of data for research. Use of data for research - King's College Hospital NHS Foundation Trust. Published nd. Accessed August 26, 2021. https://www.kch.nhs.uk/research/use-of-data-for-research

28. Health Research Authority. Patient information and health and care research. Health Research Authority. Published May 5, 2021. Accessed August 26, 2021. https://www.hra.nhs.uk/information-about-patients/

29. Barts Health NHS Trust. Privacy. Published nd. Accessed March 2, 2022. https://www.bartshealth.nhs.uk/privacy

30. Barts Health NHS Trust. Research Data Sharing Policy. Published online 2019. https://www.bartshealth.nhs.uk/download.cfm?ver=17355

31. Guy's and St Thomas' NHS Foundation Trust. Use of data. Published nd. Accessed March 3, 2022. https://www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx#na

32. Homerton University Hospital Foundation Trust. Privacy Notice (your health records). Homerton University Hospital Foundation Trust. Published 2019. Accessed March 3, 2022. https://www.homerton.nhs.uk/privacy-notice-your-health-records

33. Homerton University Hospital Foundation Trust. Privacy Notice: Your health records and how they are used. Published online 2019. Accessed March 3, 2022. https://www.homerton.nhs.uk/download/doc/docm93jijm4n3222.pdf?amp;ver=9972

34. Kingston Hospital NHS Foundation Trust. Privacy Notice. Kingston Hospital. Published nd. Accessed March 3, 2022. https://kingstonhospital.nhs.uk/privacy-policy/

35. The Royal Free London NHS Foundation Trust. Privacy notice | For patients, carers and visitors | The Royal Free. Published nd. Accessed March 3, 2022. https://www.royalfree.nhs.uk/patients-visitors/privacy-notice/

36. The Royal Free London NHS Foundation Trust. Research | Privacy notice | For patients, carers and visitors | The Royal Free. Published nd. Accessed March 3, 2022. https://www.royalfree.nhs.uk/patients-visitors/privacy-notice/research/

37. West Hertsfordshire Hospitals NHS Trust. Patient Privacy Notice v1.0. Published online nd. Accessed March 3, 2022. https://www.westhertshospitals.nhs.uk/patientinformation/documents/Patient_Privacy_Notice_v1.0.pdf

38. Whittington Health NHS Trust. Privacy Notice. Published nd. Accessed March 3, 2022. https://www.whittington.nhs.uk/default.asp?c=33205

39. Health Research Authority. *Confidentiality Advisory Group Precedent Set Categories.*; 2020. https://s3.eu-west-

2.amazonaws.com/www.hra.nhs.uk/media/documents/confidentiality-advisory-group-precedent-set-criteria.pdf

40. MHRA, Health and Care Research Wales, NHS Scotland, Health and Social Care, NHS Health Research Authority. Joint Statement on Seeking Consent by Electronic Methods. Published online September 2018. https://www.hra.nhs.uk/documents/1588/hra-mhra-econsent-statement-sept-18.pdf

41. Apgar VMD. A Proposal for a New Method of Evaluation of the Newborn Infant. *Curr Res Anesth Analg*. 1953;32(4):260-267.

42. Ministry of Housing, Communities, & Local Government. *The English Indices of Deprivation 2019*.; 2019:31. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/835115/IoD2019_Statistical_Release.pdf

43. Juster RP, McEwen BS, Lupien SJ. Allostatic load biomarkers of chronic stress and impact on health and cognition. *Neurosci Biobehav Rev*. 2010;35(1):2-16. doi:10.1016/j.neubiorev.2009.10.002

44. Li Y, Rosemberg MAS, Dalton VK, Lee SJ, Seng JS. Exploring the optimal allostatic load scoring method in women of reproductive age. *J Adv Nurs*. 2019;75(11):2548-2558. doi:https://doi.org/10.1111/jan.14014

45. National Institute for Health and Care Excellence [NICE]. *Antenatal Care for Uncomplicated Pregnancies*.; 2019.

46. Seiti G, Tsikimi I. UCLH Antenatal Care Guideline. Published online 2018.

47. Rodriquez EJ, Kim EN, Sumner AE, Nápoles AM, Pérez-Stable EJ. Allostatic Load: Importance, Markers, and Score Determination in Minority and Disparity Populations. *J Urban Health*. 2019;96(1):3-11. doi:10.1007/s11524-019-00345-5

48. Li Y, Dalton VK, Lee SJ, Rosemberg MAS, Seng JS. Exploring the validity of allostatic load in pregnant women. *Midwifery*. 2020;82:102621. doi:10.1016/j.midw.2019.102621

49. Thangaratinam S, Khan R, Blott M, Nelson-Piercy C, Williams D, Relph S. *Guidance for Maternal Medicine Services in the Coronavirus (COVID-19) Pandemic*. Royal College of Obstetricians & Gynarcologists; 2020. https://www.rcog.org.uk/globalassets/documents/guidelines/2020-12-09-guidance-for-maternal-medicine-services-in-the-coronavirus-covid-19-pandemic.pdf

50. Morris E, Draycott T, O'Brien P, et al. *Coronavirus (COVID-19) Infection in Pregnancy*. Royal College of Obstetricians & Gynarcologists; 2020. https://www.rcog.org.uk/globalassets/documents/guidelines/2020-10-14-coronavirus-covid-19-infection-in-pregnancy-v12.pdf

51. Ross-Davie M, Lambert J, Brigante L, et al. *Guidance for Antenatal and Postnatal Services in the Evolving Coronavirus (COVID-19) Pandemic*. Royal College of Obstetricians & Gynarcologists; 2020. https://www.rcog.org.uk/globalassets/documents/guidelines/2020-10-21-guidance-for-antenatal-and-postnatal-services-in-the-evolving-coronavirus-covid-19-pandemic-v3.pdf

52. Cox JL, Holden JM, Sagovsky R. Detection of Postnatal Depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry*. 1987;150(6):782-786. doi:10.1192/bjp.150.6.782

53. Meyer IH, Rossano L, Ellis JM, Bradford J. A brief telephone interview to identify lesbian and bisexual women in random digit dialing sampling. *J Sex Res*. 2002;39(2):139-144. doi:10.1080/00224490209552133

54. Herek GM. Hate Crimes and Stigma-Related Experiences Among Sexual Minority Adults in the United States: Prevalence Estimates From a National Probability Sample. *J Interpers Violence*. 2009;24(1):54-74. doi:10.1177/0886260508316477

55. Harris KM, Udry JR. National Longitudinal Study of Adolescent to Adult Health (Add Health), 1994-2008 [Public Use]: Version 18. Published online 2008. doi:10.3886/ICPSR21600.V18

56. Meyer IH, Frost DM, Hammack PL, Lightfoot M, Russell ST, Wilson BDM. Generations Study Wave 3 Questionnaire and Measures Sources. Published online 2018. https://static1.squarespace.com/static/54f4cc0be4b0014ec19fcbab/t/5b845e91cd8366c5699ca931/1535401619530/Generations+Study+Wave+3+Questionnaire+and+Measure+Sources_WEB.pdf

57. English D, Bowleg L, del Río-González AM, Tschann JM, Agans R, Malebranche DJ. Measuring Black Men's Police-Based Discrimination Experiences: Development and Validation of the Police and Law Enforcement (PLE) Scale. *Cultur Divers Ethnic Minor Psychol*. 2017;23(2):185-199. doi:10.1037/cdp0000137

58. National Institutes of Health. National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), Wave 2. Published 2007. https://healthdata.gov/dataset/national-epidemiologic-survey-alcohol-and-related-conditions-nesarc-iii

59. Williams DR, Yan Yu, Jackson JS, Anderson NB. Racial Differences in Physical and Mental Health: Socio-economic Status, Stress and Discrimination. *J Health Psychol*. 1997;2(3):335-351. doi:10.1177/135910539700200305

60. Wheaton B. The nature of stressors. In: Horwitz A, Scheid TL, eds. *A Handbook for the Study of Mental Health: Social Contexts, Theories, and Systems*. Cambridge University Press; 1999.

61. Flanagan BE, Gregory EW, Hallisey EJ, Heitgerd JL, Lewis B. A Social Vulnerability Index for Disaster Management. *J Homel Secur Emerg Manag*. 2011;8(1). doi:10.2202/1547-7355.1792

62. Carver CS, Weintraub JK, Scheier MF. Assessing Coping Strategies: A Theoretically Based Approach. *J Pers Soc Psychol*. 1989;56(2):17. doi:10.1037//0022-3514.56.2.267

63. Carver CS. You Want to Measure Coping But Your Protocol's Too Long: Consider the Brief COPE. *Int J Behav Med*. 1997;4(1):10. doi:10.1207/s15327558ijbm0401_6

64. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The Multidimensional Scale of Perceived Social Support. *J Pers Assess*. 1988;52(1):30-41. doi:10.1207/s15327752jpa5201_2

65. Vedam S, Stoll K, Martin K, et al. The Mother's Autonomy in Decision Making (MADM) scale: Patient-led development and psychometric testing of a new instrument to evaluate experience of maternity care. *PLoS ONE*. 2017;12(2). doi:10.1371/journal.pone.0171804

66. Jimenez-Torres GJ, Wojna V, Rosario E, et al. Assessing health-related resiliency in HIV+ Latin women: Preliminary psychometric findings. *PLoS ONE*. 2017;12(7). doi:10.1371/journal.pone.0181253

67. Frost DM, Meyer IH. Measuring Community Connectedness among Diverse Sexual Minority Populations. *J Sex Res*. 2012;49(1):36-49. doi:10.1080/00224499.2011.565427

68. Porter TJ. Moral and political identity and civic involvement in adolescents. *J Moral Educ*. 2013;42(2):239-255. doi:10.1080/03057240.2012.761133

69. Pancer SM. *The Psychology of Citizenship and Civic Engagement*. Oxford University Press; 2015.

70. Caracelli VJ, Greene JC. Data Analysis Strategies for Mixed-Method Evaluation Designs. *Educ Eval Policy Anal*. 1993;15(2):195-207.

71. Polkinghorne D. *Narrative Knowing and the Human Sciences*. SUNY Press; 1988.

72. Riessman CK. *Narrative Methods for the Human Sciences*. Sage Publications, Inc; 2008:x, 251.

73. Goutaudier N, Bertoli C, Séjourné N, Chabrol H. Childbirth as a forthcoming traumatic event: pretraumatic stress disorder during pregnancy and its psychological correlates. *J Reprod Infant Psychol*. 2019;37(1):44-55. doi:10.1080/02646838.2018.1504284

74. Maxwell JA, Mittapalli K. Realism as a Stance for Mixed Methods Research. In: *SAGE Handbook of Mixed Methods in Social & Behavioral Research*. SAGE Publications, Inc.; 2010:145-168. doi:10.4135/9781506335193.n6

75. Elliott J. *Using Narrative in Social Research*. SAGE Publications Ltd; 2005. doi:10.4135/9780857020246

76. Creswell JW, Creswell JD. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. 5th ed.; 2018.

77. Goldberg AE, Ross LE, Manley MH, Mohr JJ. Male-partnered sexual minority women: Sexual identity disclosure to health care providers during the perinatal period. *Psychol Sex Orientat Gend Divers*. 2017;4(1):105-114. doi:10.1037/sgd0000215

27 APPENDICES

The following twenty (20) appendices make up the materials that will be used for this study. The individual files will be stored in the study file. The documents, with their current versions, include:

1. Peer Review Documentation
    a. L+F_Peer-Review-Confirmation-Form_DQ-signed.docx
    b. L+F_Peer-Review-Confirmation-Form_SZ-signed.docx
    c. L+F_Peer-Review-Confirmation-Form_VS-signed.docx
    d. L+F_ Review Remarks_12FEB20.docx
    e. L+F_Review Remarks_for-V3.docx

2. Sampling Frame Calculations
    a. L+F-Sampling_Frame_17Feb22.xlsx

3. Email Recruitment Protocol
    a. L+F_Email-Recruitment-Protocol_V1-3.docx

4. Main Study Eligibility Questionnaire
    a. L+F_Eligibilty-Questionnaire_v1-1.pdf

5. Patient Information Sheet – Main Study
    a. L+F_PIS_V3-2.docx
    b. L+F_PIS_V3-2.pdf

6. Participant recruitment email
    a. L+F_Recruitment-Email_V2-8.docx

7. Study pamphlet
    a. L+F_InformationLeaflet_V1-2.pdf

8. In-Clinic Poster
    a. L+F_In-clinic-Study-Poster_V1-4.pdf

9. Recruitment Script
    a. L+F_Recruitment Script_V1-2.docx

10. Recruitment contact slip
    a. L+F_Contact-Slip_V2-1.docx

11. Social Media Images (with site logo placeholders)
    a. L+F Twitter 1 v1-2.jpg
    b. L+F Twitter 2 v1-2.jpg
    c. L+F Twitter 3 v1-2.jpg
    d. L+F Facebook 1 v1-2.jpg
    e. L+F Facebook 2 v1-2.jpg
    f. L+F Facebook 3 v1-2.jpg
    g. L+F Instagram 1 v1-2.jpg
    h. L+F Instagram 2 v1-2.jpg
    i. L+F Instagram 3 v1-2.jpg
    Note: Localised versions of the above are provided to each site
    j. Study_Opt-out_V1-1_Facebook.jpg
    k. Study_Opt-out_V1-1_Instagram.jpg
    l. Study_Opt-out_V1-1_Twitter.jpg

12. Participant Consent Form – Main Study
    a. L+F_Consent-Form_v2-1_main.pdf

13. REDCap Information Sheet from Website
    a. L+F_REDCap-Info.pdf

14. Documentation on the Data Safe Haven
    a. L+F_Data-Safe-Haven.pdf

15. Quantitative Measures, Panel Surveys
    a. L+ F_Survey-One_v1-1.pdf
    b. L+F_Survey-Two_v1-1.pdf

16. Journal Screener Survey
    a. L+F_Journal-Screener_v1-1.pdf

17. Participant Consent Form – Sub-study
    a. L+F_Consent-Form_v1-1_Sub-study.pdf

18. Patient Information Form – Sub-study
    a. L+F_PIS-substudy_V1-2.docx
    b. L+F_PIS-substudy_V1-2.pdf

19. Journal Format Questionnaire
    a. L+F_Journal-Type-Questionnaire.pdf

20. At-home Journal Activities
    a. L+F_DigiJournal_V2-3.pdf
    b. L+F_Qualitative-Journal_V2-3.pdf

21. Journal Submission Form
    a. L+F Journal Submission Form_v1.pdf