Parents' and children's informed and voluntary consent to heart surgery
This record is based on the protocol submitted to the IRAS HRA during 2018 with updated details added in January 2021 to show the actual progress of the research

Chief Investigator:
Professor Katy Sutcliffe, University College London Institute of Education
Funded by:
British Heart Foundation
Sponsored by:
University College London (UCL)
R&D / Sponsor Reference Number(s): 18/0478
Study IRAS Registration Number: 248332
UCL Data protection registration: Z6364106/2018/08/56

February 2019, approval was granted by NHS HRA (19/LO/0073) and Hampstead Research Ethics Committee (ID 248332), by the Institute of Education UCL (REC1188) and, in September 2019, by the HRA-Confidentiality Advisory Group (19/CAG/0148)

STUDY SUMMARY

Identifiers	
IRAS Number	248332
REC Reference No	See above
Sponsor Reference No	18/0478
Other research reference number(s) (if applicable)	Data protection Z6364106/2018/08/56
Full (Scientific) title	Parents' and children's informed and voluntary consent to heart surgery
Health condition(s) or problem(s) studied	Paediatric cardiac conditions
Study Type i.e. Cohort etc	Qualitative study
Target sample size	220, 60 children, up to 120 parents and 40 practitioners
STUDY TIMELINES	
Study Duration/length	18 months full time
Expected Start Date	1st October 2018 or as soon after as possible
End of Study definition and anticipated date	31st March 2020 This was later amended to part-time research, 6th November 2018 to 5th May 2021.
1.Key Study milestones 2.With revised planned dates 3. Actual dates	Prepare background 6/11/2018-14/1/2019; Data collection in two hospitals extended to allow access for any final visits towards the end of the project 15/11/2018-5/5/2021; Beginning analysis and writing reports from 1/2/2019; Complete reports 5/5/2021. November 2018 to September 2019. Although work on application for ethics approval began in April 2018, approval was

	not fully granted until September 2019 when permission for access to the hospitals and honorary contracts were arranged. The long delay greatly disrupted the research. Data collection in two hospitals: September 2019 to February 2020, with hospital staff, children having elective heart surgery and their parents. The COVID-19 pandemic ended the observations and interviews in hospitals, and direct contact with families and hospitals staff, as well as elective surgery. Interviews continued by phone and skype. Begin analysis and writing of reports from 1/2/2020; Complete reports 5/5/2021.
FUNDING & Other	
Funding	British Heart Foundation
Other support	Insert details of the non-financial support given, and the names & contact details of all organisation providing the non-financial support Time, academic and professional support from Dept of Social Science UCL and the two hospitals, GOSH and Evelina.
STORAGE of SAMPLES (if applicable)	
Human tissue samples	N/A
Data collected / Storage	N/A
KEY STUDY CONTACTS	Full contact details including phone, email and fax numbers
Chief Investigator	Prof Katy Sutcliffe Email: katy.sutcliffe@ucl.ac.uk 10 Woburn Square, London WC1H ONR, 0207 612 6239

KEY ROLES AND RESPONSIBILITIES

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

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

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

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

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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.

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1 INTRODUCTION

This research is intended to increase understanding of the views and experiences of children aged 6-15 years having heart surgery, their needs, hopes and fears, in order that parents and practitioners may provide children with more research-based information and support. The aim is to contribute to ways of involving children in the decision making process before heart surgery, so that their acceptance or consent, as well as their parents' consent, are well informed and voluntary. The research will also examine children's, parents and staff views about the age of consent, and when children become competent to give consent to heart surgery 'as well as their parents can'.

2 BACKGROUND AND RATIONALE

The high financial and emotional costs of disputes between families and clinicians about informed consent were highlighted by the Charlie Gard case (2017) *and the Bristol Inquiry into Children's Heart Surgery (*Kennedy, 2001*)*. Research has also shown psychological morbidity in terms of young patients' avoidable fear and misunderstandings (Bull, 2016; Harris, 2015; Honeyman, 2016). Brierley and Larcher (2016) call for new evidence to inform clearer debate and guidance relating to minors' consent. Confusions and uncertainties in law, ethics, psychology and clinical practice about children's competence to understand and consent, which can undermine practical respect for children, are summarised here, with our plans to help to clarify and resolve them.

Informed and willing (voluntary) consent involves the processes of being informed, asking questions, understanding and reflecting in the light of personal values on the choices and their risks and benefits. Then, as freely as possible within unavoidable constraints such as illness, it involves making, becoming committed to and signifying the decision to give or withhold consent (Nuremberg Code 1947; Helsinki 1964/2013). Anglo-American law emphasises the individual responsibility of the person who signs the consent form. Aiming to be clear and efficient and to prevent litigation, clinical staff therefore tend to inform and concentrate solely on that person, usually the parent if the patient is a child. US law, which influences UK and European Commission law (EC, 2007) assumes that whenever minors are concerned parents/guardians will be the sole consent-givers (Biggs, 2009; Gillam, 2016; Guggenheim, 2005; McDougall et al., 2016; Montgomery, 2016; Ross, 2006).

Children's 'assent' (USNCP, 1977), another US-led concept with global influence, has replaced children's 'consent' in recent versions of the *Declaration of Helsinki* (WMA [1964] 2013), in guidelines (ABPI, 2004) and law (EC, 2007). Assent has neither the long history nor the definite meaning and detailed standards of consent (*Nuremberg Code,* 1947; WMA [1964] 2013) and it does not require that the child be informed at all. Assent could mean that the child expresses agreement or else does not actively refuse, which children may be too uninformed, afraid, shy or embarrassed to do. EC (2007) allows adults merely to 'consider' but then override children's views. It assumes that parents always know and support their child's 'presumed will'. Yet research shows how even young children need to be informed and involved at different levels (Alderson, 1993; Alderson et al., 2006a, 2006b; Bluebond-Langner, 1978; CE 2011; Coyne and Gallagher, 2011; Harris, 2015; Honeyman, 2016; Kilkelly, 2011; Sutcliffe, 2016). Some senior clinical staff believe that children's acceptance or resistance can affect their post-operative recovery (Alderson and Goodwin, 1993).

EC (2007) is criticised for raising confusing inconsistencies with English *Gillick* law (Alderson, 2012; Biggs, 2009). Backed up by NHS (2016) guidance, English *Gillick* law [1985] was summarised: 'as a matter of law the parental right to determine whether or not their minor children below the age of 16 will have medical treatment terminates if and when the child achieves a sufficient understanding and intelligence to understand fully what was proposed [and] sufficient discretion to enable him or her to make a wise choice'. The *Convention on the Rights of the Child* (UNCRC, 1989) ratified by every government except the US, respects the rights of children (1) to be informed, (2) to express their views freely in

all matters that affect them, and (3) to have due weight taken of their views (by adults) in accordance with the age and maturity of the child. *Gillick* [1985] adds (4) competent minors can be 'the main decider' about consent to surgery (Alderson and Montgomery, 1996).

From their first years, children are meaning-makers. Unless, for example, the need for painful surgery is explained to them, irrationally but deeply psychologically, children may feel ashamed and guilty and to assume they are being punished for reasons that are too awful for the adults to explain (Miller 1983).They may be more worried by their imagined ideas than they would be by having accurate information and reassurance (Harris 2015; Honeyman 2016). They can feel very confused, guilty, lonely, afraid of further unexpected unexplained punishment, and unable to tell adults about their fears. People in middle and old age still have intense detailed memories of their admissions for heart surgery when they were highly aware children as young as 5-years old (Bull, 2016).

The legal rulings pose problems for how children's 'understanding and intelligence', 'discretion' and 'wisdom', and their legal competence to consent may be defined and assessed clearly. Informed consent is the legal device that transfers blame from the surgeon onto the patient who willingly/voluntarily undertakes risks in order to access the hoped-for benefits. Especially if surgery is not successful, minors' ability to bear responsibility and potential blame may be doubted. These doubts can be avoided if the parents' consent alone is required, or when there is an agreed minimum legal age of consent, but English law does not set a clear age (Donaldson, 1991, 1992; *Gillick* [1985]; Montgomery, 1992, 2016; Weisleder, 2007).

Not all healthcare staff have the training, skill, confidence or time to talk to children about serious life-threatening illness and treatment, to listen to their fears and respond to their doubts, questions and unspoken cues. Uncertainties about whether, when and how children ought to be informed and involved in decisions complicate the already complex discussions before high-risk heart surgery. Paradoxically, although discussions may be harder when the child is very ill, for children who feel well and symptom-free, the decision to undergo surgery may need still more explanation, imaginative courage and trust (Bull, 2016; Harris, 2015). If surgery is not to be forced onto a resisting child, the child has to have some understanding of, and agreement with, the surgeon's advice that the untreated condition is worse than the pain, dangers and scarring of surgery. Yet the BHF sponsored survey about how 81 young people were informed before surgery never mentions consent in the survey questions or replies (Harris, 2015). The young people listed numerous questions they had felt unable to ask, and a nurse commented, 'I'd say at least 90% of the teenagers we see have no idea what condition they've got [and] mostly the parents don't know either.'

Academic research is not always helpful. Psychologists' emphasis on gradual age-stage development through immature childhood and adolescence towards mature adulthood has wide influence, ranging from the caution in US and British guidance (AAP, 1995, 2016; ABPI, 2004) to Australian ethicists who ignore all minors' views about their surgery (Gillam, 2016; McDougall et al., 2016). Sociologists, however, have observed young children's competencies being respected by their parents, doctors and nurses (Alderson 1993; Alderson and Goodwin 1993; Alderson, et al., 2006; Percy-Smith and Thomas, 2010; Sutcliffe, 2010) and being strongly influenced by the information, support and respect that are given or withheld by the responsible adults To summarise: The research will investigate practical, legal, ethical, psychological and social confusions, which complicate clinicians' and parents' respect for the informed and willing consent or at least cooperation of young patients. The confusions can potentially lower clinical and therapeutic standards, erode trust in doctor-patient relationships, increase stress and uncertainties for all concerned, and increase the risk of disputes and even litigation. Traditional emphasis on the individual consent-giver also overlooks how parents and children share information, negotiate decision-making, and journey together towards the crucial acceptance of surgery as less harmful than the untreated disease. Regardless of who eventually signs the form, to some extent, the child has to understand this logic, if treatment is not to be misunderstood as unnecessary cruelty. Understandably, adults are reluctant to explain to children their

dangerous and potentially fatal heart condition, and the research will examine the benefits, dangers and challenges of honestly informing young patients, and of not informing and involving them. The research will therefore require very high ethical standards, which are considered at length in Alderson (1990, 1993) and in Alderson and Morrow (2011).

3 THEORETICAL FRAMEWORK

The research will investigate the practical, legal, ethical, psychological and social confusions, which complicate clinicians' and parents' respect for the informed and willing consent or at least cooperation of young patients.
Evidence and analysis of children's, parents' and practitioners' views and experiences during the consent process are intended to help staff and families to raise standards, and reduce mistrust, disputes and avoidable fear and confusion.
The research will therefore require very high ethical standards, which are considered at length in Alderson (1990, 1993) and in Alderson and Morrow (2011).
Our analysis will be informed by critical realist analysis of such themes as agency (Archer 2003) and childhood (Alderson, 2013, 2016) and the three levels of reality (Bhaskar, 1998) to ensure that it is 1) interpretive (respecting people's perceptions, memories and accounts), 2) empirical (respecting medical realities and actual events and discussions) and 3) also concerned with powerful underlying influences on children's experiences (including the history, economics, politics, power and limitations of the NHS context and of paediatric cardiology).

4 RESEARCH QUESTIONS

Primary research question:
How are young patients and their parents informed and involved in decision-making about heart surgery?
Secondary questions:
What are the risks, benefits and challenges of informing and involving children?
How is children's competence assessed?
How do adults give children serious and distressing information about their heart condition and treatment and the risks of non-treatment?
In what various ways interviewees think that children should be informed and involved, supported and respected or protected from complex distressing knowledge?
In the opinion of each child and the parents, at what age the child can be or become competent to give informed willing consent as well as the parents can, although the parents may still be the formal legal consent-giver?
How might the information, decision sharing and care might be improved?
How might the related confusions in law, ethics and practice be resolved?

4.1 Objectives

To interview 60 child patients aged 6 to 15 years, and one or both of their parents;
To interview 40 healthcare professionals based in two London paediatric cardiac units;
To carry out observations in clinics, on wards and in consultant meetings;
To obtain new evidence of current professional practices in paediatric cardiology, of what does or does not work well when clinical staff and parents do or do not inform and involve children in major healthcare decisions;
To examine how clinicians and parents define, assess and influence children's competence to be informed and involved in decision-making;
To relate children's and parents' experiences to their social contexts and influences, including current NHS provision and policies, daily practices and problem-solving, family background and the child's medical history;
To analyse the data and write reports for medical, nursing and lay journals and websites;

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To make recommendations that support present effective clinical practices and standards, law, ethics and guidelines or else propose improvements.

4.2 Outcomes

From our analyses we will:-

- Produce reports for a range of medical, nursing and lay journals and websites showing the practical importance of the findings to each relevant profession.
- Actively disseminate our findings through conferences, invited lectures, websites and policy networks to discuss with professionals the relevance and implementation of the recommendations.

5 STUDY DESIGN

5.1 Design

The complex social relations and practices surrounding children's consent that are outlined above are best understood through analytical qualitative research. The research design will combine in-depth interviews with observations of activities and discussions in the clinic. The interviews will provide detailed insights about the views and experiences of children, parents and staff about sharing information and decision-making. Observations will provide further insights about this process of decision-making as it plays out in practice. Data will be analysed thematically and interpreted using critical realism.

5.2 Data collection

5.2.1 Interviews

Semi-structured interviews will be conducted with 40 clinical staff once, and with 60 young patients, and one or both of their parents shortly after heart surgery and three to six months later (total 280 interviews). There will be only one parent interview per family. Parents will be interviewed singly or jointly. Children and parents may choose whether they are present during one another's interviews. Although we have allowed one hour per interview in case this is necessary(see excel schedules form), in practice, children's interviews may last from 15 minutes to over an hour. When their interviews are a few days after surgery, children may prefer two short sessions to one longer one. Follow up interviews are likely to be shorter. Parents' first interviews will be approximately one hour, and second interviews may be closer to 40 minutes depending on the child's recovery. First interviews will be held in the hospitals if the child is well enough. Otherwise, like the follow up interviews, they will be held in the family's home, or in the hospital when the child has an outpatient appointment.
The interview schedules (see Appendix 9-11) are based on our previous research.The interviews will be conducted by the research team who are experienced in interviewing children, parents and healthcare professionals. The audio-recorded interviews will be face-to-face, unless families would prefer their follow up interview to be by phone, instead of the researcher visiting their home.

5.2.2 Observations

We will also observe daily activities in the wards and outpatient clinics and the medical meetings where cases are discussed. We will observe discussions before surgery between practitioners and children and parents to see how children are informed, prepared and listened to. Observations will be undertaken by the postdoctoral researcher and general clinic observations will be recorded via note-taking.

5.3 Data analysis

Thematic analysis will be used to systematically identify, analyse, organise, describe, and report recurring or salient themes found within the data. Our analysis will be informed by critical realist analysis of such themes as agency (Archer 2003), childhood (Alderson, 2013,

2016) and three levels of reality Bhaskar, 1998) to ensure that it is 1) interpretive (respecting people's perceptions, memories and accounts), 2) empirical (respecting medical realities and actual events and discussions) and 3) also concerned with powerful underlying influences on children's experiences (including the history, economics, politics, power and limitations of the NHS context and of paediatric cardiology).

5.4 Additional work

To support this work we will:

- convene three advisory groups of a multi-disciplinary expert panel, parents and young people to inform on the focus and direction of the research
- set up a webpage about the research to inform families, staff and other researchers about the nature and progress of the research
- undertake critical multi-disciplinary literature reviews to inform and structure the research.

Update: The advisers met on 14/2/2019. 14/2/2020 and 11/2/2021.

6 STUDY SETTING

The research will be conducted in two centres, the Evelina London Children's Hospital and Great Ormond Street Hospital.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility criteria

Inclusion Criteria

- Young heart surgery patients
  - Aged 6 to 15 years
  - In-patient on the wards or out-patient in the clinic
  - We will seek variation in terms of heart conditions, prior experience of treatment, gender, ethnicity and socio-economic status.
- Parents/guardians of the young patients
  - For children who have two parents/guardians present we will seek to include either or both according to the preference of the families.
- Healthcare Practitioners in the paediatric cardiac units
  - We will seek to involve a range of professions, grades, years of experience, ethnicity, and both genders.

Update: The 40 professional interviews included four staff in children's heart information and support charities and with additional interviews with four external experts.

Exclusion Criteria

Non-English speaking groups will not be included in interviews, as interpreters will not be employed. We will ask their visiting relative and friends who speak English to explain the observation parts of the research to them if they are near our observation sessions.

7.2 Sampling

7.2.1 Size of sample

Interviews will be undertaken with 40 clinical staff once, and 60 young patients and their parents shortly after heart surgery and three to six months later (total 280 interviews). Observations will likely reach a broader cohort of families and staff.

7.2.2 Sampling technique

A purposive sample of staff and families will be approached in the wards and the clinics and they will be asked if they are willing to be interviewed. Those who express interest will be

given information sheets and the offer to discuss the sheet. After they have had time to read the sheet, and if they decide to volunteer to be interviewed, they will be shown the consent form, to work through with the interviewer.
The sample will include children across the age range 6 – 15 years, with different heart conditions and medical histories. The staff will include a range of professions, grades and years of experience and, like the children's group, an approximate gender balance

7.3 Recruitment

7.3.1 Sample identification

Identification of child and parent participants: The Principal Investigators (who are paediatric cardiologists) will review their clinic appointments and admission lists and inform the research team about potential participant families. The researchers will not see any medical records.

Identification of staff participants: Identification will be done by researchers acting under arrangements with the responsible care organisations. The Principal Investigators will inform staff about the study by distributing leaflets and putting up posters (Appendix 4 and 5). We have also been invited to speak to medical and general staff meetings. During the months of general observations in the wards and clinics, the research team will identify the range of cardiologists, surgeons, nurses, psychologists, chaplains, teachers, and other professionals to invite to be interviewed.

7.3.2 Consent

Informing families and staff about the research

Staff and families in the clinic and wards will be given information sheets (Appendix 1-4) to increase general knowledge about the research. Posters and handout leaflets will explain the observations and invite opt-out consent to observations and opt-in consent to interviews (Appendix 5). The researchers will wear a large 'Researcher' badge to alert everyone about the role. No names will be recorded on observation notes unless the person concerned had consented to take part in the research.

Obtaining consent for interviews

Some families will receive the information leaflet (Appendix 1-3) with their outpatient appointment letter days before they attend the hospital. Others will be given the leaflets while they are waiting in the clinic. The clinicians say they will allow one researcher to observe their outpatient clinics with the group of other observing junior and visiting doctors. The researchers will talk informally to families and get to know many of them. Some children and parents who are interested in the research will be asked for permission for the researcher to go with them to the echocardiology or other investigations. Families will be asked to take part in interviews some time after they have met there researcher in the clinic or in the ward where they stay for a day before surgery, or during the days while the child is recovering after surgery.

Interviews will take place a few days after surgery. Those who express interest in taking part in interviews will have seen the information sheet days or weeks before they discuss it with the researcher in detail to ensure they have understood it. They will then be given the consent forms (Appendix 6-7). Children who agree to be interviewed will have the option of signing their form, or of their parent recording that they have witnessed their child's informed and willing oral agreement. (Earlier research has found that some 15 year olds who willingly consent to surgery still did not want to sign the consent form.) The children's consent form also has a space for a parent's signature. The consent forms follow the General Data Protection Regulation 2018 and the HRA guidelines, including advice on writing clear forms with intended readers in mind.

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Obtaining consent for observations

The general research observations of routines in the clinics and wards are vital. They enable the researchers to understand the daily realities that the families and staff are talking about. They can analyse the processes of consent in their social and clinical contexts. They can appreciate the wide variety of the children's and adults' experiences, views, needs and responses.

Great care will be taken to gain explicit informed consent for interviews, audio-recorded discussions between doctors and families, for observing procedures on individuals such as echocardiography, and for spending time with families in the child's private curtained bed space.

For general observations of groups of children and adults in more public areas, such as in the clinics and playrooms, opt out consent will be relied on. We will display posters and give hand-out leaflets about this (Appendix 5). We will be alert to anyone who seems uncomfortable and leave the area. When we make notes we will not identify anyone unless they have given formal consent.

Update. Much of the delay with the ethics application involved queries about observations without consent. These were eventually approved by the HRA-Confidentiality Advisory Group.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

The risks the researchers will watch for and guard against are that children and adults might possibly feel, while they are being observed or interviewed, that the research is too intrusive, or upsetting, or that it raises ideas they want to avoid thinking about, or they might feel guilty or ashamed or judged, for example, as a 'not good-enough parent'. The researchers will be alert to spoken and unspoken cues if interviewees seem uneasy, and will offer to pause, or might change the subject. In our experience, interviewees who become upset tend to welcome the chance to talk about their worries, and say they want to continue with the interview. Social researchers aim to establish mutual trust with interviewees so that they can relax and feel able to talk freely to someone who understands their views. Semi-structured schedules enable interviewee and interviewer to progress through topics together as far as the interviewee wishes.

Some interviews will be in participants' homes. The UCL lone work policy will be adhered to, and described in the protocol under risk as well as in the IRAS.

Each interviewee will be assured that their views will not be repeated to anyone else in the unit, and before their data are shown to anyone in reports, they will be pseudonymized. Interviewees will be invited to choose a research name.

The only exception, and the other main risk, is if the researcher thinks a child might be at risk of physical or psychological harm. This will have to be reported to the lead consultant, or a member of the nursing or psychology team.

Regular research team meetings provide time for the researchers to talk about anything that they are concerned about, and ways to address any problems and questions the participants might raise.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

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

- The Sponsor considers the procedure for obtaining funding from the British Heart Foundation to be of sufficient rigour and independence to be considered an adequate peer review.

The study was deemed to require regulatory approval from the following bodies: Research Ethics Committee and the Health Research Authority. Each approval will be obtained before the study commences.

8.3 Peer review

In order to obtain funding from the BHF for this project the proposal has been anonymously peer reviewed by three independent reviewers and approved by the BHF. The full account of the peer review and our responses is contained in Appendix ADD the following provides an overview of this:-

Reviewer 1: I really like this application: *It addresses an incredibly important question - at what stage and how do you involve children (6-16 years) in decisions and consent about their heart surgery. The applicants have all of the necessary experience for doing this. The application builds on relevant preliminary data and consultation with patients, their parents and other stake holders (including the BHF) about what some of the key concerns are. It seems likely to me that the outcomes will have impact and it is good value for money.*

Reviewer 2: *The proposed study addressed an interesting and important issue about involvement of children in informed consent for heart surgery. I appreciate the challenges faced by parents, professionals and children during this process and agree that an enhanced understanding of their views about children's involvement in informed consent process is needed.*

Reviewer 3: *This application comes from just two people. They have a health policy and social science background. One is a major leader in informed consent. They have excellent social science qualitative skills. The project aims to explore and understand current practice for informed consent for children undergoing heart surgery. It will produce rich data that will establish current practice in one centre. This is an under researched area and it is very important.*

8.4 Patient and public involvement (PPI)

The project will draw on the well-tested and developed methods and questions of a 1989-1991 study with 120 young patients, their parents and 70 hospital staff about their consent, mainly to orthopaedic surgery (Alderson, 1993). This developed from a 1983-1988 study of parents' consent to children's heart surgery (Alderson, 1990), by adding interviews with children. We have also used similar methods in studies with children with type 1 diabetes (Alderson et al., 2006a, 2006b; Sutcliffe, 2010). Topic guides for our semi-structured interviews will encourage and respectfully support interviewees to explore their complex experiences, hopes and fears.

Since this is potentially such sensitive research, and because the interviews will be conducted at a critical time around surgery, we will undertake two phases of pilot work.

1) We will discuss the questions and approaches with our advisory panels of children and parents to check they are adequate and appropriate.
2) We will use an initial set of questions and approaches during the first eight interviews with children, then adapt or improve them for the rest of the sample as necessary.

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We have also asked the British Heart Foundation and the Children's Heart Federation to circulate their members (professionals, parents and young people) with news about this application, and invite them to add to our research questions, and forward any responses anonymously on to us. Concern was expressed about 'support for families whose children have not consented to surgery and who need to make arrangements to live with that decision', and who need support that could include 'timely reviews, prognosis, increasing support in community and family counselling'.

Besides the wealth of responses from children and adults in our earlier research, our plans have also been informed by the recent British Heart Foundation survey of young people's views about surgery (Harris, 2015). There are strong common themes of parents and children trying to make sense of medical information.

Our research has been questioned for being too stressful and intrusive for families during the crisis of major surgery, and for wrongly challenging parents' authority and family harmony. However, we have had no complaints from interviewees, very few refusals, and on hearing about our research some people ask to be involved. Many have welcomed being able to talk to us in depth, and many also say they hope to benefit others by helping with our research.

Some Research Ethics Committees are cautious about approving research with children in hospital, with the negative effect that children may be silenced. The health services are then not able to learn from children's valuable views on which services are beneficial and which could be improved.

8.5 Protocol compliance

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

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

8.6 Data protection and patient confidentiality

8.6.1 Data sources

With consent, interviews will be audio-recorded and transcribed by UK Transcription Services. Observations will be recorded via note-taking. No medical notes will be seen.

8.6.2 Data storage

All data in electronic and hard copy records and research notes will be stored in a locked cabinet in Professor Alderson's office, which is not used by any other staff, and on encrypted computers at UCL or on encrypted laptops at home. Only the research team will have access to these. The audio recordings may be transferred to desktop/ laptop on our return home or to the office, after being taken there in a secure bag. Data will be kept securely, while reports are written, until the end of 2023, and will then be stored for 20 years in line with UCL Record Retention Policy.

8.6.3 Data transfer

Only the researcher concerned and the transcriber will see or hear the raw data (notes, audio-recordings). The researcher will replace real names with pseudonyms in all transcripts made by the researchers or returned by the transcriber. No real names of anyone who has not signed a consent form will be recorded at all. All emails and discussions among the

research team and the advisory groups with supervisors, with other academic records, will use encrypted UCL systems.

Update: the transcription company used a secure encrypted system for the transfer or recordings.

8.6.4 Data confidentiality and anonymity

All use of transcriptions and notes in draft and final reports and any other potentially public documents will be pseudonymized, with further care to protect anonymity of any participants at extra risk of being identified by slightly changing their details. The list of real names and contact details (for follow up details, to respond to participants' inquiries, to send them research report, to convene advisory meetings) will be kept separate from all the records, printed or on computers.

If any participants opt out and request this, all their data will be removed and destroyed up to two months before the end of the project, when papers will have been submitted to journals. Details may still be removed from papers at participants' request. Data will only be used for this project, not for future research.

8.7 Indemnity

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

8.8 Access to the final study dataset

Only the researcher team and the commercial transcriber will see or hear the raw data (notes, audio-recordings). The data will not be used for any secondary analysis.

9 DISSEMINATION POLICY

- The study data will be owned by the research team. All three will have rights to publish from the data.
- On completion of the study, the data will be analysed and a final study report prepared. Funding from the BHF will be acknowledged within publications.
- We will also provide brief reports for participants on the outcome of the study.
- The study protocol and full study report will be made publicly available on the UCL IRIS website (http://iris.ucl.ac.uk/iris/).
- We plan also to produce several open-access publications for academic journals as well as to actively disseminate our findings through conferences, invited lectures, websites and policy networks to discuss with professionals the relevance and implementation of the recommendations.

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11 APPENDICES

11.1 Appendix 1 – Required documentation

Include here supplementary information and documents that will support the protocol and information contained therein, e.g. PIS, ICF, schedule visit, assessment tools, delegation log, case report forms, questionnaires, scales, tables, charts, diagrams, manufacturer's brochures.
PA Note 7/9/18: I cannot see how to insert them when this file is in track change mode so have sent them separately but in a format that will be easier to insert.

1. Children's information sheet
2. Young people's information sheet
3. Parents' information sheet
4. Professionals' information sheet
5. A4 poster and A5 leaflet
6. Children's and young people's consent form
7. Parents' consent form
8. Professionals' consent form
9. Children's and your people's interview schedule
10. Parents' interview schedule
11. Professionals' interview schedule

11.2 Appendix 2 – Schedule of events

Method	Timeline				
	0-2 months	3-6 months	6-9 months	9-15 months	16-18 months
Prepare access to hospitals	✓				
Keep literature reviews updated	✓	✓	✓	✓	✓

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Set up and maintain webpage	✓	✓	✓	✓	✓
Set up three advisory groups, convene three meetings	✓		✓		✓
Data collection, observations, interviews	✓	✓	✓	✓	
Follow up interviews with families			✓	✓	✓
Data analysis and report writing			✓	✓	✓

Update: The 18 month full time research plan was transferred into a 30 month part time research plan, November 2018 to May 2021.

1. Children's information sheet – To print on yellow paper folded to an A5 leaflet

Parents' and children's consent to heart surgery

Institute of Education

Information for children

Please will you help with my research?

My name is Rosa. I am asking 60 children and their parents to tell me what they think about how they are informed and listened to and cared for when they have heart surgery. I also hope to observe the care sometimes.

This leaflet explains my research. I hope you will find it helpful. I'll be happy to answer any of your questions and concerns.

I have set out the questions you might want to ask, with my answers, so you can think about them before you decide if you would like to take part.

Please contact me if you want more details and/or if you would like to join the project.

Why is the research being done?

Doctors and nurses want to know more about what children think about having a heart operation.

I plan to listen to children, to their parents and healthcare staff, and write reports about their views. With permission, I also plan to observe their care.

The aim is for everyone involved to know more about the kinds of information and care children and parents find work well.

What questions will the project ask?

- How much do you want to be told, and prepared, and listened to before you have the surgery?
- What information and care do you find helpful or unhelpful while you stay in the hospital?
- Do you have ideas about how the information and care could be improved?
- What would you say to another child your age who is waiting for a heart operation?
- When do you think you were or will be old enough to share in deciding that you need to have a heart operation and to give consent?

Who will be in the project?

Sixty children aged 6 to 15 years, their parents, and 40 hospital staff in two London hospitals.

Do I have to take part?

You decide if you want to take part or not.

Even if you say `yes' to be interviewed and observed, you can change your mind and stop doing the research at any time.

And you can tell me if you want to have a break.
If you don't want to answer some questions, just say `pass'.

You do not have to tell me anything unless you want to. And you don't have to give me a reason if you say `no' or `stop'. You can also ask me or ask a nurse to tell me to stop my observations at any time.

Whether you help me or not, you will still go on having just the same care at the hospital.

What will happen to me if I take part?
Before your operation, if you agree, I will meet you at the clinic or in the ward to see the kinds of information and care you are having. I will ask some children, parents and doctors if I can audio record them talking together.

When you feel well enough after your operation I will talk to you about your views. I hope to audio-record you and we might talk for between 15 minutes and an hour. We could meet in the hospital or, if you agree, at your home.

There are no right or wrong answers. It is your own views that matter. I will also ask to talk to your mother or father.

Could there be any problems for me if I take part?
I hope you will enjoy talking to me. A few people get upset when talking about their lives, and I can put them in touch with someone to help them, if they wish.

If you have any complaints about the project, please tell me, or you could ask a nurse to tell me, or you could contact Katy Sutcliffe Katy.sutcliffe@ucl.ac.uk.

Will doing the research help me?
I hope you will enjoy helping me. But my main aim is to help children in the future by writing reports about useful ways to inform and listen to them.

Who will know if I am in the research, or what I have talked about?

People in the hospital may see you taking part in the research, project, but I will not talk to them about what you tell me or what I see.

The only time I might have to break this promise is if I think you or someone else might be at risk of being hurt. If so, I will talk to you first about the best thing to do.

I will keep the audio-tapes and notes about you in a safe locked place until May 2021. In all the records on my computer and in all my reports, I will change your name, so people can read about your ideas but not know they are yours. This is to respect your privacy.

Will I know about the research results?

I will send you a short report in Summer 2021, and longer reports too, if you want to see them.

If you take part, please keep this leaflet with your copy of your consent form.

Thank you for reading this leaflet.

Researcher: Rosa, R.Mendizabal@ucl.ac.uk
Dept. Social Science, University College London, 18 Woburn Square, London WC1H ONR
Chief investigator and data controller: Prof Katy Sutcliffe katy.sutcliffe@ucl.ac.uk,
Co-Investigator: Prof Priscilla Alderson p.alderson@ucl.ac.uk.
Principal Investigator at GOHS: Dr Nathalie Dedieu
Principal Investigator at Evelina: Dr Hannah Belllsham-Revell
Reviewed and approved by the Health Research Authority and by the [add name]
Research Ethics Committee Approval no. [to add]
Data Protection Officer: Lee Shailer oversees respect for privacy in all use of the research data, data-protection@ucl.ac.uk, no. Z6364106/2018/08/56
Leaflet version 2, February 2019.
Funder: British Heart Foundation. Sponsor: University College London (UCL).
The study sponsor (UCL) and data controller (Katy Sutcliffe) are responsible for looking after the information we collect about you and using it properly.

2. Young people's information sheet – folded to an A5 leaflet

Parents' and children's consent to heart surgery

Institute of Education

Information for young people

Please will you help with my research?

My name is Rosa. I am asking 60 children and young people and their parents to tell me what they think about the ways they are informed and listened to and cared for when they have heart surgery. I also hope to observe the care sometimes.

This leaflet explains my research. I hope you'll find it helpful. I'll be happy to answer any of your questions or concerns.

I have set out the questions you might want to ask, with my answers, so you can think about them before you decide if you would like to take part.

Please contact me if you want more details and/or if you would like to join the project.

Why is the research being done?

Doctors and nurses want to know more about what young people think about having a heart operation.

I plan to listen to young people, parents and healthcare staff, and write reports about their views. With permission, I also plan to observe their care.

The aim is for everyone involved to know more about the kinds of information and care young people find work well.

What questions will the project ask?

- How much do you want to be told, and prepared, and listened to before you have the surgery?
- What information and care do you find helpful or unhelpful while you stay in the hospital?
- Do you have ideas about how the information and care could be improved?
- What would you say to another person your age who is waiting for a heart operation?
- When do you think you were or will be old enough to share in deciding that you need to have a heart operation and to give consent?

Who will be in the project?

Sixty young people in two London hospitals, aged 6 to 15 years, their parents, and 40 hospital staff.

Do I have to take part?

You decide if you want to take part or not.
Even if you say `yes' to be interviewed and observed, you can drop out at any time.
And you can tell me if you want to stop, or have a break.
If you don't want to answer some questions, just say `pass'.
You do not have to tell me anything unless you want to. And you don't have to give me a reason if you say `no' or `stop'. You can also ask me or ask a nurse to tell me to stop my observations at any time.
Whether you help me or not, you will still go on having just the same care at the hospital.

What will happen to me if I take part?

Before your operation, if you agree, I will meet you at the clinic or in the ward to see the kinds of information and care you are having. I will ask some children, parents and doctors if I can audio-record them talking together.
When you feel well enough after your operation I will talk to you about your views. I hope to audio-record you and we might talk for between 15 minutes and an hour. We could meet in the hospital or, if you agree, at your home.
There are no right or wrong answers. It is your own views that matter. I will also ask to talk to your mother or father.

Could there be any problems for me if I take part?

I hope you will enjoy talking to me. A few people get upset when talking about their lives, and if they want to stop, we stop. I can put you in touch with someone to help you, if they wish. If you have any complaints about the project, please tell me or you could ask a nurse to help you to report your problem. Or you could contact Katy Sutcliffe Katy.sutcliffe@ucl.ac.uk.

Will doing the research help me?

I hope you will enjoy helping me. But my main aim is to write reports that will help very many young people in the future,
by helping the staff to know more about useful ways to inform and listen to them.

Who will know if I am in the research, or what I have talked about?

People in the hospital may see you taking part in the research, project, but I will not talk to them about what you tell me or what I see.

The only time I might have to break this promise is if I think you or someone else might be at risk of being hurt. If so, I will talk to you first about the best thing to do.

I will keep the audio-tapes and notes about you in a safe locked place until May 2021. In all the records on my computer and in all my reports, I will change your name, so people can read about your ideas but not know they are yours. This is to respect your privacy.

Will I know about the research results?

I will send you a short report in Summer 2021, and longer reports too, if you want to see them.

If you take part, please keep this leaflet with your copy of your consent form.

Thank you for reading this leaflet.

Researcher: Rosa, R.Mendizabal@ucl.ac.uk
Department of Social Science, University College London, 18 Woburn Square, London WC1H ONR
Chief investigator and data controller: Prof Katy Sutcliffe katy.sutcliffe@ucl.ac.uk,
Co-Investigator: Prof Priscilla Alderson p.alderson@ucl.ac.uk.
Principal Investigator at GOHS: Dr Nathalie Dedieu
Principal Investigator at Evelina: Dr Hannah Belllsham-Revell
Reviewed and approved by the Health Research Authority and by the [add name] Research Ethics Committee Approval no. [to add]
Data Protection Officer: Lee Shailer oversees respect for privacy in all use of the research data, data-protection@ucl.ac.uk, no. Z6364106/2018/08/56
Leaflet version 2 February 2019.
Funder: British Heart Foundation. Sponsor: University College London (UCL).
The study sponsor (UCL) and data controller (Katy Sutcliffe) are responsible for looking after the information we collect about you and using it properly.

3. Parents information sheet - to print on pale green paper folded to an A5 leaflet.

UCL Institute of Education

Parents' and children's consent to heart surgery

Information for parents
Please will you help with my research?

My name is Rosa. I am asking 60 children and young people and their parents to tell me what they think about the ways they are informed and cared for. I also hope to observe the care sometimes.
This leaflet explains my research. I hope you will find it helpful. I'll be happy to answer any of your questions or concerns.

I have set out the questions you might want to ask, with my answers, so you can think about them before you decide if you would like to take part.

Why is the research being done?
Healthcare professionals want to know more about what children and parents think about having heart surgery.
I plan to listen to children, parents and healthcare staff, and write reports about their views. With permission, I also plan to observe their care.
The aim is for everyone involved to know more about the kinds of information and care that children, young people and their parents find work well.

What questions will the project ask?

- How much do children and parents want to be told and prepared and listened to before heart surgery?
- What information and care do you find helpful or less helpful before and after the surgery?
- Do you have ideas about how the information and care could be improved?
- When do you think your child was or will be old enough to share in deciding that he or she needs to have a heart operation and to give consent?

Who will be in the project?

Sixty children and young people aged 6 to 15 years, in two London hospitals, and also their parents, and 40 hospital staff.

Your rights

It is your right to decide if you want to take part or not.

You are free to withdraw at any time, to refuse to be observed or answer questions, and to say if you wish to stop or to have a break, without having to give a reason.

Whether you take part in the research or not, your child's care will not be affected in any way.

What does taking part involve?

If you agree, I will meet you at the clinic and in the ward to observe the kinds of information and care you and your child are having. I will ask some children, parents and doctors if I can audio-record them talking together.

I would like to interview you about your views a few days after your child's operation, and again a few months later. We could meet in the hospital or, if you agree, at your home. I hope to audio-record you, and we might talk for between 30 and 60 minutes. I will ask you to sign a consent form, and the recordings will be sent to a transcription company.

Could there be any problems for me if I take part?
I hope you will enjoy talking to me. A few people get upset when talking about their child's heart surgery, and if they want to pause or stop I respect their wishes. I can put them in touch with someone to help them, if they would like that.

If you have any complaints about the project, please tell me or you could ask a nurse to help you to report your problem, or you could contact Katy Sutcliffe katy.sutcliffe@ucl.ac.uk who will pass on your complaint to the UCL sponsor's office. If you are concerned about privacy, please contact data-protection@ucl.ac.uk.

Will taking part in the research help me?
I hope you will enjoy helping me. But my main aim is to write reports that will help very many children and parents in the future by helping the staff to know more about useful ways to inform and listen to them.

Who will know if I am in the research?
Other people in the hospital may see you taking part in the research, but I will not talk to them about what you tell me or what I observed.

The only time I might have to break confidentiality is if there is a concern about child protection.

If so, I will talk to you first about the best thing to do. I will keep the audio-tapes and notes about you in a safe locked place until May 2021. In all the records on my encrypted computer and in all my reports, I will change your name.

No one reading the reports will be able to identify you, to respect your privacy and your child's privacy.
We will store the anonymous transcripts safely until 2041, then destroy them. If you withdraw from the study before 2021, we will delete all your records.

Will I know about the research results?
I will send you a short report in Summer 2021, and longer reports too, if you want to see them.
For more details about the research and your rights please see [add project website].

Thank you for reading this leaflet.
If you take part, please keep this leaflet with your copy of your consent form. Please contact me if you would like to have more details and/or join the project.

Postdoctoral researcher, Rosa, R.Menidzabal@ucl.ac.uk
Department of Social Science, University College London,
18 Woburn Square, London WC1H ONR
Reviewed and approved by the Health Research Authority and by the [add name] Research Ethics Committee Approval no. [to add]
Leaflet version 2, February 2019.
Chief investigator and data controller: Prof Katy Sutcliffe katy.sutcliffe@ucl.ac.uk,
Co-Investigator: Prof Priscilla Alderson p.alderson@ucl.ac.uk.
Principal Investigator at GOHS: Dr Nathalie Dedieu
Principal Investigator at Evelina, Dr Hannah Belllsham-Revell
Data Protection Officer: Lee Shailer oversees respect for privacy in all use of the research data, data-protection@ucl.ac.uk, no. Z6364106/2018/08/56
Funder: British Heart Foundation. Sponsor: University College London (UCL).
The study sponsor (UCL) and data controller (Katy Sutcliffe) are responsible for looking after the information we collect about you and using it properly.

4. Professionals information leaflet - o print on pale blue paper folded to an A5 leaflet

Institute of Education

Parents' and children's consent to heart surgery

Information for healthcare professionals

Please will you help with my research?

My name is Rosa. I am a postdoctoral researcher and I'm interviewing 40 staff in two London paediatric cardiac units, and also 60 children and their parents. I also hope to observe the care sometimes.

I am researching their views about how children and parents are informed, cared for and listened to when a child has heart surgery. I am also observing the daily work in the hospitals.

This leaflet explains my research. I hope you will find it helpful. I have set out the questions you might want to ask, with my replies. Please contact me if you would like to have more details, or if you have any concerns, and if you would like to be interviewed.

Please let me know if you do not want me to observe your work

Why is the research being done?

The aim is to provide staff in paediatric cardiac units with information about children's and parents' views, experiences and needs. Interview transcripts and observation notes will be analysed to compile reports for medical and nursing journals.

The intention is for everyone involved to know more about the kinds of information and care children and their parents find work well.

What questions will the project ask?

- How do children and parents want to be informed, prepared and listened to before heart surgery?
- What kinds of information and care do they find helpful or unhelpful before and after the surgery?
- Do families and healthcare professionals have ideas about how the information and care might be improved?
- When are children old enough to share in deciding if they need to have a heart operation and to give consent?

Your rights

It is your right to decide if you agree to be observed and want to be interviewed. If you do take part in an interview, you are free to withdraw at any time, to refuse to answer questions, and to say if you wish to stop or to have a break, without having to give a reason. The research will not affect your legal and employment rights in any way.

What does taking part involve?

I appreciate the staff have little spare time, but I hope you will allow me to observe your work and sometimes ask questions and/or audio-record some episodes of care. Audio-taped interviews, in a private space in the hospital, will take between 30 and 60 minutes. I will ask you to sign a consent form, and the recordings will be sent to a transcription company.

Could there be any problems for me if I take part?

I hope you will enjoy talking about your work to me. Very occasionally a few people feel anxious or unhappy when talking about certain aspects of their work, and if they want to pause or stop I respect their wishes.
If you have any complaints about the project, please tell me, or you could contact Professor Katy Sutcliffe katy.sutcliffe@ucl.ac.uk who will pass on your complaint to the UCL sponsor's office. If you are concerned about privacy, please contact data-protection@ucl.ac.uk.

Will I benefit from taking part in the research?

I hope you will enjoy helping me. But my main aim is to write reports that will benefit very many children and parents in the future, by helping the healthcare professionals to know more about useful ways to inform and listen to them.

Who will know if I am in the research, or what I have talked about?

Staff and families in the hospital may see you helping with the research. But I will not talk to anyone about what you tell me or what I observe, unless there is a concern about child protection. If so, I will discuss that with you first.

I will keep all the audio-tapes and observation notes in a locked cabinet until May 2021. In all records on my encrypted computer and in my draft and published reports, I will use pseudonyms. To respect everyone's privacy I will make sure they cannot be identified in any reports. We will store the anonymous transcripts safely until 2041, then destroy them. If you withdraw from the study before 2021, we will delete all your records.

Will I know about the research results?

I will send you a short report in Summer 2021, and longer reports too, if you want to see them.
For more details about the research and your rights please see [add project website].

If you take part, please keep this leaflet

Thank you for reading this leaflet.

Postdoctoral Researcher: Rosa, R.Mendizabal@ucl.ac.uk
Department of Social Science, University College London,
18 Woburn Square, London WC1H ONR
Chief investigator and data controller: Prof Katy Sutcliffe
katy.sutcliffe@ucl.ac.uk,
Co-Investigator: Prof Priscilla Alderson p.alderson@ucl.ac.uk.
Principal Investigator at GOHS: Dr Nathalie Dedieu
Principal Investigator at Evelina: Dr Hannah Belllsham-Revell
Reviewed and approved by the Health Research Authority and by the [add name] Research Ethics Committee Approval no. [to add]
Data Protection Officer: Lee Shailer oversees respect for privacy in all use of the research data, data-protection@ucl.ac.uk, no. Z6364106/2018/08/56.
Leaflet version 2, February 2019.
Funder: British Heart Foundation. Sponsor: University College London (UCL).
The study sponsor (UCL) and data controller (Katy Sutcliffe) are responsible for looking after the information we collect about you and using it properly.

Institute of Education

Parents' and children's consent to heart surgery

IRAS no: 28332

Consent Form

for patients aged 6-15 years

Thank you for thinking about this research.

		Please initial only if you agree
1	I have understood the information sheet, dated 28.02.19 version 2 All my questions have been answered.	
2	I know that I do not have to take part in any of the research unless I want to. I can say 'stop', or I can leave the research at any time. I do not have to give any reason. And this will not affect my medical care or my legal rights.	
3	I agree to take part in audio-recorded interviews, and to some of my discussions with doctors being observed, and some being audio-recorded, if everyone involved gives consent.	
4	I know that my part in the study will be strictly private and no one in the hospital will be told what I say, unless there is a question about child protection. Only the research team will see all research records, which will be securely stored.	
5	I agree to details about me and my views being used in reports about the research, with my private research name.	
6	I agree to take part in the research.	

Name of participant Date Signature

I consent to my child taking part in this research

Name of parent/guardian Date Signature

If the young patient or donor is willing to take part in the research,

but prefers not to actually sign the form, please will the parent/guardian tick this box ☐

Name of researcher Date Signature

This consent form will be securely stored in UCL premises.

Institute of Education

Parents' and children's consent to heart surgery

IRAS no: 28332

Consent form for patients aged 16 years

Please complete this consent form after you have read the study information sheet.

		Please initial if you agree
1	I confirm that I have read and understood the information about the study on the information sheet, dated 08/02/2019 version 2. All my questions have been answered.	
2	I understand that I am free to withdraw at any time without giving any reason. And this will not affect my child's medical care or my legal rights.	
3	I consent to take part in audio-recorded interviews.	
4	I agree to some of my discussions with doctors being observed if the doctor agrees, and to some being audio-recorded if everyone involved gives consent.	
5	I understand that my part in the study will be strictly confidential and nothing I say will be repeated to anyone in the hospital, unless there is a question about child protection. Only the research team will have access to all the audio, typed and written research records, which will be securely stored.	
6	I consent to take part in the study	

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature

This consent form will be securely stored in UCL premises.

Institute of Education

Parents' and children's consent to heart surgery

IRAS no: 28332

Consent form for parents

Please complete this consent form after you have read the study information sheet.

		Please initial if you agree
1	I confirm that I have read and understood the information about the study on the information sheet, dated 08/02/19 version 2 All my questions have been answered.	
2	I understand that I am free to withdraw at any time without giving any reason. And this will not affect my child's medical care or my legal rights.	
3	I consent to take part in audio-recorded interviews.	
4	I agree to some of my discussions with doctors being observed if the doctor agrees, and to some being audio-recorded if everyone involved gives consent.	
5	I understand that my part in the study will be strictly confidential and nothing I say will be repeated to anyone in the hospital, unless there is a question about child protection. Only the research team will have access to all the audio, typed and written research records, which will be securely stored.	
6	I consent to take part in the study	

_____ _____ _____

Name of participant Date Signature

_____ _____ _____

Researcher Date Signature

This consent form will be securely stored in UCL premises.

Institute of Education

Parents' and children's consent to heart surgery

IRAS no: 28332

Consent form for healthcare professionals

Please complete this consent form after you have read the study information sheet.

		Please initial only if you agree
1	I confirm that I have read and understood the information about the study on the information sheet, dated 08/02/19 version 2. All my questions have been answered.	
2	I understand that I am free to withdraw at any time without giving any reason, and this will not affect my legal rights.	
3	I consent to take part in an audio-recorded interview.	
4	I agree to some of my discussions with patients and parents being observed, and to some being audio-recorded if everyone involved gives consent.	
5	I understand that my part in the study will be strictly confidential and nothing I say will be repeated to anyone in the hospital, unless there is a question about child protection. Only the research team will have access to all the audio, typed and written research records, which will be securely stored.	
6	I consent to take part in the research.	

_____ _____ _____

Name of participant Date Signature

_____ _____ _____

Researcher Date Signature

This consent form will be securely stored in UCL premises.