

FACULTY OF LIFE SCIENCES AND EDUCATION
FACULTY ETHICS SUB GROUP LOW RISK APPLICATION FORM

Information for applicants

This form should be completed for all research studies that require **LOW RISK ethics review** within the Faculty of Life Sciences and Education.

If **none** of the points from the HIGH RISK ELIGIBILITY CRITERIA apply, then the research can be considered Low Risk and this Low Risk Ethical Application form should be completed and submitted for consideration to the Faculty Ethics Sub Group Secretary.

PLEASE NOTE: If you are not sure, it is your responsibility to seek guidance from your Research Supervisor, the Faculty Ethics Champion, or USW Research Governance Manager.

Research recruitment and data collection must not commence until approval from the Faculty Ethics Sub Group (FESG) has been granted - where approval is required. For the avoidance of doubt, data collection cannot begin until you have received written confirmation of approval from the faculty ethics sub group.

This form should be completed in line with the relevant guidelines appropriate to your area of study. For example (but not limited to) the Research Councils UK, British Education Research Association, the National Health Service, and the British Psychological Society.

Please consult the following USW documents:

- USW Research Ethics Policy, Terms of Reference and Operating Procedures for University Ethics Sub Group and Faculty Research Ethics Committees
- USW Research Governance Framework

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Overview of Proposed Study	
Name of Chief Investigator:	████████████████████
Staff or student project:	Professional Project – Module 2 MSc Acute Medicine
Faculty:	Faculty of Life and Sciences and Education
Programme of Study: (if applicable)	MSc Acute Medicine (PE4D036)
Name of Study Lead / Supervisor: (if applicable)	Supervisor – ██████████
Proposed Project Title:	Cardiac Resynchronisation Therapy in Adults with Structural Congenital Heart Disease and Chronic Heart Failure: Retrospective Study of Efficacy and Factors Predicting Success.
Start date:	upon approval
Proposed end date:	5 TH July 2021
Co-investigators:	N/A
Code(s) of conduct to be followed or the guidelines appropriate to your area of study or discipline:	<ul style="list-style-type: none"> • USW Ethics Guidance for Research and Consultancy USW Research Governance Framework • WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS • Data Protection Act 2018
<p>Brief outline of your Research Study (500-750 words) to include:</p> <ol style="list-style-type: none"> 1. Rationale, research aims and/or questions 2. Research setting (e.g. is a lone worker policy needed?) 3. Your professional role (if appropriate) 4. Your relationship to participants (if any) 5. Details of sample and sampling strategy 6. Methods of data collection¹ 7. Data analysis 	
<p>My professional role is doctor at University Hospitals Birmingham NHS Foundation Trust (UHBFT). I have no relationship to participants.</p> <p><u>Introduction:</u></p>	

¹ Data collection methods could include interviews, group interviews, focus groups, questionnaires, observation, visual data, assessment or measurement, documentary analysis. Please specify how the data will be recorded (if appropriate) i.e. note taking, audio recording, visual recording.

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Cardiac resynchronisation therapy (CRT) is a form of device therapy established for use in patients with chronic heart failure. Adults with congenital heart disease (CHD) comprise a unique population with complex and heterogenous anatomical and physiological differences compared to the general population with chronic heart failure. Generally, guidelines for the use of CRT in adults with CHD are similar to those without CHD. There are no randomised trials investigating the efficacy of CRT in this population and evidence is from small retrospective observational studies. Little is known about potential patient factors, anatomical considerations, procedural factors and device programme parameters which may predict and therefore improve response to CRT in adults with CHD.

Aims:

The primary aim of this study is to evaluate the effectiveness of CRT in adults with CHD in terms of electrophysiological, functional and symptomatic response to device therapy.

Secondly, this study will aim to identify which factors predict favourable response to CRT, including patient selection, baseline electrophysiological parameters, anatomy and surgical history, procedural considerations such as lead placement and device settings.

Methods, Data collection and Analysis:

Firstly, a comprehensive literature review will be conducted. The literature review will focus on the evidence for CRT in adults with CHD, discussing the challenges and limitations of the evidence in this group. Evidence will then be examined in detail to identify factors which may predict positive response to CRT, for example certain congenital anatomical variants or particular device settings.

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The primary research in this study will be retrospective in nature, using data collected for service evaluation and improvement purposes at a tertiary centre for adults with CHD, integrating findings from this large centre with what is already known about the subject area. Data will be collected from electronic health records of all patients with CHD who have had a primary CRT implant or device upgrade at UHBFT, with an expected population of approximately 50 patients. Only patients with structural CHD will be included, therefore those with congenital complete heart block and congenital dilated cardiomyopathy, for example, will be excluded. Patients will be known to adult CHD services and will therefore be >18 years old at the time of device implantation or upgrade.

Baseline data collection will include underlying diagnoses, surgical history (number of operations, operation details), anatomical variant (systemic left ventricle, systemic right ventricle or univentricular). Baseline ECG data (QRS duration, QRS morphology) and imaging findings (most recent pre-procedure echocardiographic ejection fraction %) will also be collected. Symptoms according to NYHA classification from most recent clinic visit prior to device insertion or upgrade will be recorded. Data on procedural and technical factors will be collected, including type of device (CRT-D or CRT-P), number of leads, lead placement and baseline device settings.

The primary outcome measure of this study will be response to CRT. Positive response to CRT will be defined as improvement in New York Heart Association (NYHA) class by at least one category and/or improvement in systemic ventricular function by one class. Primary outcome data gathered will therefore include symptoms (NYHA class) at 4-6 weeks and again at subsequent follow-up, up to 12 months post-procedure. Echocardiography findings up to 12

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months post-procedure will be recorded and compared to pre-procedure ejection fraction. Secondary outcome data collected will include ECG morphology and QRS duration (% change following device), immediate, 4-6 week and longer-term procedure or device complications and whether ECG or echocardiography-based optimisation occurred. Where longer term data is available, outcomes including subsequent hospitalisations, transplant listing and mortality will also be gathered.

Statistical analysis will be performed using SPSS. Statistical tests will compare the mean or median of data before and after CRT implant, depending on the normality of distribution of data. For example, the Chi-squared statistical test will be used to calculate a P value for the binary primary outcome measure of positive response to CRT (yes/no). P values <0.05 will be considered statistically significant. Multivariate regression analysis will be used to identify factors that predict good response to CRT in terms of improvement in NYHA class, systemic ejection fraction and ECG parameters (% change in QRS duration).

Findings of this project will be presented locally at the CHD multi-disciplinary team meeting. It will also aim to be presented at a national conference and submitted for publication in a peer-reviewed journal.

Responsibilities to Participants

1. Voluntary Informed Consent

How will you gain access to the participants?

N/A

Data collection is part of a clinical service evaluation of the ACHD service at University Hospitals Birmingham NHS Foundation Trust with regard to patient selection for cardiac resynchronisation therapy. As data will be collected from electronic healthcare records retrospectively, in accordance with the Data Protection Act 2018 and anonymised at the point of collection, no informed consent from individual participants is needed. Local

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audit/service evaluation approval has been sought from the Clinical Audit Registration and Management System (CARMS) and approval is attached to this document.	
How will you provide participants with the information they need about the study? Please attach a copy of the information that will be provided to the participants where appropriate	
As mentioned in the previous section, due to the retrospective nature of data collection as part of a service evaluation and improvement project, informed consent from individual participants will not be sought and therefore information will not be provided directly to each participant.	
How patient data may be used is set out by University Hospital Birmingham NHS Foundation Trust in their privacy notice (https://www.uhb.nhs.uk/privacy-notice/patients) and is accessible by the general public and patients of the Trust. This informs patients that anonymised or pseudo-anonymised data may be used for audit, service evaluation and research purposes and that this is permitted for the “provision of health or social care or treatment or the management of health of social care systems and services” under Chapter 2, Section 9 of the Data Protection Act 2018.	
How will you ensure that you have informed consent from the participants? Please attach a copy of the consent form(s) that will be provided to the participants where appropriate	
N/A – see above	
How will you inform participants of their right to withdraw from the study?	
N/A – see above	
Information about use of data is provided by University Hospital Birmingham NHS Foundation Trust in their privacy notice (https://www.uhb.nhs.uk/privacy-notice/patients)	
How will you inform participants of the complaints procedure?	
N/A – see above	
Information about complaints procedure is provided by University Hospital Birmingham NHS Foundation Trust in their privacy notice (https://www.uhb.nhs.uk/privacy-notice/patients)	
Checklist for managing Voluntary Informed Consent - Tick all that apply	
Please confirm that all respondents will be given an appropriate level of information about and be given adequate time to think about the information before being asked to agree to participate	N/A
Please confirm that all participants taking part in an interview, focus group, observation (or other activity which is not questionnaire based) will be informed that anything they say which either: <ul style="list-style-type: none"> • Suggests harm to a person might be caused • Indicates potential or actual professional misconduct • Outlines criminal activity 	N/A

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Then, the information will need to be report to the appropriate authorities.	
Please confirm that all participants completing a questionnaire will be informed on the Information Sheet that returning the completed questionnaire implies consent to participate. On-line: this message will be presented at the start (with a reminder at the end) of the questionnaire as part of an implied consent statement.	N/A
Please confirm that all participants being asked to provide personal data (sensitive and standard) will be told which legal basis is being cited for collecting and processing their personal information – this should be conveyed on the consent form and information sheet. In accordance with the new General Data Protection Regulations (GDPR).	N/A
Please confirm that all respondents will be told that they can: <ul style="list-style-type: none"> • withdraw at any time, • ask for their data to be removed from the project until it is no longer practical to do so (e.g. following anonymization or, when a report has been written and submitted). 	N/A
Please confirm that personal data will only be retained for the purpose of this research and will be disposed of as soon as possible (e.g., immediately following anonymization).	✓
Duty of Care to the Participants	
How will you ensure the participants' well-being during the research?	
N/A	
What information will you provide to the participants at the end of their involvement in the study (if appropriate)? Is it necessary to hold personal contact information for this purpose?	
N/A	
Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisations funding the research that may give rise to a possible conflict of interest? If so, please describe these below and any arrangements in place to mitigate the conflicts.	
N/A	
Researcher Safety	
Are there any issues around researcher safety and if so how will you address those? Are there any risks? What are the arrangements in place to mitigate risk?	
N/A	

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2. Managing Data	
How will you ensure the confidentiality and anonymity of the research participants?	
Data will be collected retrospectively from electronic health records by the primary investigator. Medical records containing patient identifiable data will only be accessed from secure Trust computers and the password protected data collection tool will remain saved on a secure Trust computer and not taken or transferred off-site. All data collected will be anonymised at the point of data collection, with all patient identifiable information removed prior to data analysis. Any data or research information saved on a personal computer will be fully anonymised with no patient identifiable information and password protected/encrypted.	
Checklist for managing issues of confidentiality and anonymity Tick all that apply	
Questionnaires will be returned anonymously and indirectly	N/A
Questionnaires and/or interview transcripts will only be identifiable by a unique identifier (e.g. code/pseudonym).	N/A
Lists of identity numbers or pseudonyms linked to names and/or addresses will be stored securely and separately from the research data.	<input checked="" type="checkbox"/>
All names of people, places or organisations, which could lead to the identification of individuals or organisations, will be changed.	<input checked="" type="checkbox"/>
I confirm that my research records will be held securely at USW according to the Data Protection Act 1998 and 2018 (DPA), as well as the new General Data Protection Regulations (GDPR) in accordance with USW guidelines	<input checked="" type="checkbox"/>
I confirm that I will not use the research data for any other purpose WITHOUT contacting the Faculty Ethics Champion or USW Research Governance Officer in advance. This includes the sharing of research data with people outside of the research team.	<input checked="" type="checkbox"/>

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Data will be stored on a personal computer and, as well as the computer being password protected/encrypted, so will any document files.	✓
How will research findings be fed back to the research participants?	
Findings will not be fed back to individual participants due to the retrospective nature of data collection as part of service evaluation. Findings will aim to be published in a peer reviewed journal accessible to the community.	
How will the research be disseminated to the wider community?	
Findings will aim to be presented at a national conference and published in a peer reviewed journal.	
Attachments	
Tick all that are included	
Data collection tools	✓
Adverts and standard letters	N/A
Information Sheet(s)	N/A
Consent Form(s)	N/A
Researcher Safety Protocol (e.g. the lone worker policy)	N/A
Other approvals, for example approval of external organisations allowing you access to their participants; or internal approvals and USW risk assessment.	✓
Applicant's Declaration	
<p>If your project is approved you must follow the process and documents you have submitted. If your application is not approved you will need to refer to this version of your application when preparing your re-submission. Please note if you intend on deviating from the approved protocol or documentation you will need to request approval for any changes. Please indicate the following:</p>	

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<p>I have read and agree to abide by the latest version of the document: Research Ethics Policy, Terms of Reference and Operating Procedures for University Ethics Sub Group and Faculty Research Ethics Committees This can be found at https://www.southwales.ac.uk/research/research-expertise/research-governance/</p>		✓
<div style="border: 1px solid black; padding: 5px;"> <p>Research Governance University of South Wales The University is committed to the following principles of good research practice. These are laid out in our USW Research Good Practice Code of Conduct which stipulates: That our research is underpinned with common values of rigour and integrity www.southwales.ac.uk</p> </div>		
<p>I have read and agree to abide by the Code(s) of Conduct identified at the start of this form</p>		✓
<p>I understand that failure to follow my approved protocol constitutes research misconduct and the policy for such offences will be followed in such an instance</p>		✓
<p>I confirm that the USW is responsible for this study</p>		✓
<p>I confirm that all procedures that will occur within the research will adhere to USW Policy on Health and Safety and that where applicable, a thorough risk assessment will be completed <i>prior to</i> the research taking place</p>		✓
<p>Print name: [REDACTED]</p>	<p>Please sign: [REDACTED]</p>	
<p>Date: 11/01/2021</p>		
<p>Supervisor's Declaration (for students). If missing, application should be rejected.</p>		
<p>If the student's project is approved they must follow the process and documents they have submitted. If their application is not approved they will need to refer to this version of their application when preparing their re-submission. Please note if you intend on deviating from the approved protocol or documentation you will need to request approval for any changes.</p>		
<p>I have read and agree to abide by the Code(s) of Conduct identified at the start of this form</p>		✓
<p>I have read the guidelines accompanying this application form and understand that failure to follow these and the approved protocol constitutes research misconduct and the policy for such offences will be followed in such an instance</p>		✓

