

CARDIFF METROPOLITAN UNIVERSITY APPLICATION FOR ETHICS APPROVAL

When undertaking a research or enterprise project, Cardiff Met staff and students are obliged to complete this form in order that the ethics implications of that project may be considered.

If the project requires ethics approval from an external agency such as the NHS or MoD, you will not need to seek additional ethics approval from Cardiff Met. You should however complete Part One of this form and attach a copy of your NHS application in order that your School is aware of the project.

The document ***Guidelines for obtaining ethics approval*** will help you complete this form. It is available from the [Cardiff Met website](#).

Once you have completed the form, sign the declaration and forward to your School Research Ethics Committee.

PLEASE NOTE:

Participant recruitment or data collection must not commence until ethics approval has been obtained.

PART ONE

Name of applicant:	Shivan Jassim
Supervisor (if student project):	Angus Robertson
School:	School of Sport
Student number (if applicable):	ST10000172
Programme enrolled on (if applicable):	MSc Sports & Exercise Medicine
Project Title:	'Return to sport after lower limb arthroplasty - why not for all?'
Expected Start Date:	01/12/2013
Approximate Duration:	4 months
Funding Body (if applicable):	N/A
Other researcher(s) working on the project:	Jenni Tahmassebi (Research physiotherapist) and Prof. Fares Haddad (Consultant Orthopaedic Surgeon) – Both University College London Hospital, London
Will the study involve NHS patients or staff?	No
Will the study involve taking samples of human origin from participants?	No

In no more than 150 words, give a non technical summary of the project
Questionnaire-based retrospective analysis of a cohort of patients that have undergone lower-limb hip or knee arthroplasty (minimum two years follow-up) to assess their participation in athletic activity before and after surgery. Purpose of investigation is to assess reasons for changes in

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participation levels of sport after joint replacement. Tools used include validated questionnaires specific to joints (Oxford Hip/Knee Score), general health (SF-12), athletic activity (UCLA) and sports activity questionnaire to investigate attitudes to sport after arthroplasty and qualitative reasons for reducing participation in athletic activity post-operatively. Patients selected from private logbook of consultant surgeon and will be contacted by telephone/post to complete questionnaires. Patient selection will be done on basis of age, co-morbidities and number of joints replaced to minimise other confounding factors. The study will aim to get results from a minimum of 50 patients although more will be contacted to ensure maximum possible study numbers.

Does your project fall entirely within one of the following categories:

Paper based, involving only documents in the public domain

No

Laboratory based, not involving human participants or human tissue samples

No

Practice based not involving human participants (eg curatorial, practice audit)

No

Compulsory projects in professional practice (eg Initial Teacher Education)

No

If you have answered YES to any of these questions, no further information regarding your project is required.

If you have answered NO to all of these questions, you must complete Part 2 of this form

DECLARATION:

I confirm that this project conforms with the Cardiff Met Research Governance Framework

Signature of the applicant:
Shivan Jassim

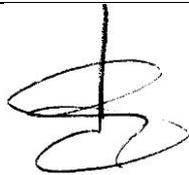
Date: 10 November 13

FOR STUDENT PROJECTS ONLY

Name of supervisor:
Angus Robertson

Date: Monday, 11 November 13

Signature of supervisor:



Research Ethics Committee use only

Decision reached:

Project approved

Project approved in principle

Decision deferred

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Project not approved <input type="checkbox"/>	
Project rejected <input type="checkbox"/>	
Project reference number: 13/11/12P	
Name: Peter O'Donoghue	Date: 29/01/2014
	
Signature:	
Details of any conditions upon which approval is dependant: Click here to enter text.	

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PART TWO

A RESEARCH DESIGN	
A1 Will you be using an approved protocol in your project?	No
A2 If yes, please state the name and code of the approved protocol to be used ¹	
N/A	
A3 Describe the research design to be used in your project	
<ul style="list-style-type: none"> - Study is a non-invasive questionnaire-based human participant study. Aim of study is to assess functional outcomes and participation levels in sporting/athletic activity following lower-limb (hip/knee) joint arthroplasty. - Patient sample will be taken from the logbook of Prof. F Haddad (Supervisor). This will be to include all lower limb arthroplasty patients and then filtered to find all patients under the age of 60 years with a single joint replaced, American Society of Anaesthesiologists (ASA) grade 1 or 2 and with a minimum period of two years from operation. Aim is for minimum of 50 patients with more likely estimates for 100. - Questionnaire will be made of 4 parts (see attached documents): 1 – Oxford Hip/Knee Score (depending on joint replaced) for joint-specific capabilities; 2 – Short Form (SF)-12 score for general lifestyle capabilities; 3 - University of California Los Angeles (UCLA) activity score for athletic/sports capabilities; 4 – Sports activity questionnaire for listing of activities performed before and after surgery, importance of athletic activity to the patient following joint arthroplasty and reasons for non-participation in activity post joint arthroplasty. - Once suitable patient list has been made, recruitment will be done by contacting patients by phone or email to gain consent for questionnaires to be sent out for completion. Participation is voluntary with no influence on subsequent care based on acceptance/refusal to take part in study. If accepted, patients will be sent questionnaires by email/post (with pre-paid return envelope). Patients will be contacted within three weeks if questionnaire not returned to improve response rate. - Once all completed and valid questionnaires have been received, results will be analysed and presented. Statistical analysis will be performed to assess any association between participation in sports and other patient variables, such as joint replaced or types of sport previously performed. 	
A4 Will the project involve deceptive or covert research?	No
A5 If yes, give a rationale for the use of deceptive or covert research	
N/A	

B PREVIOUS EXPERIENCE	
B1 What previous experience of research involving human participants relevant to this project do you have?	
Questionnaire-based project on patient knowledge of robotic and navigation systems in orthopaedic surgery. Involved self-designed questionnaire. Study performed at University College London Hospital in 2012 under supervision of Prof. Fares Haddad. Study presented at podium of British Orthopaedic Association meeting in Manchester, September 2012	
B2 Student project only	
What previous experience of research involving human participants relevant to this project does your supervisor have?	
Patient based study looking at the outcome of THR replacements. Robertson A, Lavalette D, Morgan S, Angus PD. The hydroxyapatite coated Furlong hip: outcomes in patients under the age of 55. <i>J Bone Joint Surg</i> 2005; 87-B:12-15.	

¹ An Approved Protocol is one which has been approved by Cardiff Met to be used under supervision of designated members of staff; a list of approved protocols can be found on the Cardiff Met website here

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C POTENTIAL RISKS
C1 What potential risks do you foresee?
Nil risks anticipated. Patient Reported Outcome Measure Scores (PROMS) questionnaires are given to patients routinely at follow-up from joint arthroplasty. Questionnaires are based on this, thus not deviating from routine practice. All patients are post-operative thus no influence on subsequent treatment will be made based on questionnaire.
C2 How will you deal with the potential risks?
Nil risks anticipated. Project author available to answer any questions that patients may have on the questionnaires in order to maximise compliance and minimise patient drop-out/non-participation.

When submitting your application you **MUST** attach a copy of the following:

- All information sheets
- Consent/assent form(s)

Refer to the document ***Guidelines for obtaining ethics approval*** for further details on what format these documents should take.