HSR Protocol Cover Sheet

HSR Submission Number: 10548

Title: Complication rates and Cost differences between revision hip and knee procedures transferred from outside facilities compared to normal elective pathway

Committee Review Amount: Exempt

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Sub-Investigators:

James Browne	School of Medicine, Orthopaedic Surgery
James Macdonell , MD	Medical Center, Med Center Units

Sponsor(s): N/A

Funding Grant(s): N/A

Five Year Update: NO

Location of Study:

Multi-Site Study: NO

PRC Study: NO

GCRC Study: N/A

IND N/A

IDE: N/A

Auxiliary Documents Required for Submission:	None
If applicable, submit one copy of any other you have such as:	• Questionnaires • Surveys • Manual of Operations • Package Inserts • COI Management Plan
Auxiliary Documents Required for Approval:	None

Other Documents:	NONE

Committee Conflict: NONE

Question/Answers for HSR Submission: 10548		
1.	Are you doing research with human subjects or a clinical investigation as an agent for UVa?	YES
2.	Will the IRB-HSR be the IRB of record for this protocol for the research to be done by UVa personnel?	YES
36.	Do you plan to do research with data previously collected as part of an Improvement Project (e.g. Performance Improvement, Practice Improvement, Quality Improvement) in which there was no interaction or intervention with an individual and the project only involved the use of information from UVa medical records?	YES
37.	Will all HIPAA identifiers listed below be removed/destroyed from the data prior to sharing the data outside of UVa?	YES

TEMPLATE SECTIONS

EXEMPT APPLICATION (IP)

IMPROVEMENT PROJECT: EXEMPT APPLICATION FORM

Template Version Date 07/22/15

INSTRUCTIONS AND INFORMATION

Enter responses electronically. Email this completed form and the Protocol Cover Sheet to IRBHSR@virginia.edu for IRB Review.

IRB-HSR #:18953 ***(Will be assigned by IRB Staff during pre-review.)***

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Name of Person Submitting this form: James Ryan Macdonell

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Protocol Title: Differences in costs and outcomes between total joint arthroplasty patients transferred to UVA vs. those who follow the traditional pathway

Version Date: 3/8/2016

1. **Provide a brief summary of the completed Improvement Project, a summary of the findings and your plans to share the findings outside of UVa** ***(****less than 200 words***)**. We have examined our data on readmission, cost, infection rate, complication rate, and outcomes for patients that had their hip or knee replacment scheduled through clinic at UVA (elective cases) compared to those who presented to the emergency department, had previous surgery elsewhere, and presented to clinic, or were transferred to UVA hospital for care (emergent or urgent cases). Our findings demonstrate that patients who come to our service through the emergency department or are transferred from other facilities are sicker, have more complicated problems, and require much more resources than patients who are seen by UVA surgeons from the onset of treatment. We often get cases from other facilities that have serious complications from prior surgeries that were done outside of UVA, including sepsis, poor healing, and other mechanical complications. These patients have longer lengths of stay, higher costs for care, and are at higher risk for poor outcomes, including morbidity and mortality. The data utilized in this analysis were collected as part of a QI initiative. This project will be publishable in our

total joint arthroplasty literature and will draw attention to the increased cost and resources utilized by hip arthroplasty patients who present through the emergency department or as transfers. In addition, we will be able to demonstrate that transferred patients and emergency department patients have greater morbidity and mortality compared to elective patients, which is significant information for surgeons, administrators, and providers caring for hip arthroplasty patients.

2. I confirm all of the following by checking below:

- ☒ All data was collected from clinical records at UVa for an **Improvement Project** (*e.g. Performance Improvement, Practice Improvement, Quality Improvement*).
- ☒ The completed Improvement Project did not involve an interaction/intervention with an individual , including any observation of a minor.
- ☒ No data was received from outside of UVa
- ☒ If any data was collected from students information governed by the federal FERPA regulations, such as information from Student Health, the Registrar's Office, the Office of Assessment and Studies, or the Student Information System (SIS) a date of birth was not collected.
- ☒ All HIPAA identifiers* as noted in the table below that may have been included in the data from the Improvement Project have now been removed/destroyed from all copies of the data.
- ☒ Any data from this project that is shared outside of UVa will only be shared in an aggregate or de-identified manner.

***HIPAA identifiers: Limited Data Set criteria per HIPAA under 164.514(e)**

1. Name
2. Postal address information, other than town or city, state, and zip code
3. Age or DOB if over 89 years of age
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security number
8. Medical Record number
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images

18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
19. Any other information that could be used alone or in combination with other information to identify an individual. (*e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code* .)

Data Use Agreement

IRB-HSR Protocol #18953

INSTRUCTIONS: Data being used in this protocol may meet the criteria of a Limited Data Set. To comply with HIPAA regulations the principal investigator of this protocol must sign this memo regarding Limited Data Sets. This memo must be filed with your regulatory files and kept for 6 years from the date of this determination.

This memorandum is designed to permit you to use and disclose a "Limited Data Set" of patients' health information for UVA in compliance with the HIPAA Privacy Rule, 45 CFR Parts 160 and 164, subparts A and E.1.

1. Except as otherwise specified in this memorandum, you may use and disclose the Limited Data Set for research purposes only as described above. You represent that the Limited Data Set is the minimum amount of data necessary for the conduct of the Research.

2. You agree not to use or disclose the Limited Data Set for research purposes other than as permitted by this Agreement or as otherwise required by law.

3. You agree to use appropriate safeguards as described above to prevent the use or disclosure of the Limited Data Set other than as provided for by this Agreement.

4. You agree to promptly report to the IRB for Health Sciences Research Office any use or disclosure of the Limited Data Set not described in this memo of which you become aware.

5. You agree not to attempt to identify the patients to whom the information contained in the Limited Data Set pertains in order to contact those individuals for purposes of research.

Principal Investigator

4/27/2016

Date

For IRB-HSR Use Only

IRB-HSR # 18953

Protocol Title : Differences in costs and outcomes between total joint arthroplasty patients transferred to UVA vs. those who follow the traditional pathway

The IRB-HSR confirms that this project meets the criteria of research which is exempt from federal regulations under 45CFR46.101 (b)(4).

The health information to be collected in this study may meet the criteria of Limited Data Set. Please sign and save the enclosed Data Use Agreement with your study files for 6 years.

If you need to modify the procedures in this project you must notify the IRB-HSR first to determine if the project continues to meet the criteria for exempt research.

For additional information regarding educational resources for research see http://www.virginia.edu/vpr/irb/hsr/education.html

Signed Karen Mimms **Date** 04-27-16

IRB-HSR Staff Member