NYU School of Medicine
NYU LANGONE MEDICAL CENTER

Institutional Review Board
Human Research Protection Program
1 Park Avenue | 6th Floor | New York, NY 10016
http://irb.med.nyu.edu

Application for Waiver of Authorization and/or Consent

Submission Instructions

Our website provides full instructions on submitting applications to the IRB: http://irb.med.nyu.edu/esubmission
Please contact the IRB office at 212 263-4110 with any questions.

Administrative Information

Study#	S17-01223	Date of this request	10/7/2017
Study Title	Multicenter, Prospective Registry of Hip & Knee Implants		

Role	Name	Kerberos ID/Email**	Phone	Fax
Principal Investigator	Ran Schwarzkopf	Ran.Schwarzkopf@nyumc.org	212-598-1775	
Contact Person	James Feng	James.Feng@nyumc.org	845-264-9957	

Request

In order to access or use an individual's Protected Health Information (PHI) in the conduct of research without the express authorization of the individual, you must request a waiver of authorization.

In order to conduct research without the express written consent of a human subject, you must request a waiver of informed consent.

You may also request an alteration in consent or authorization. In other words: you will be obtaining written consent but may require certain elements of the consent be altered and you will need to request an alteration in consent and authorization.

You may request a waiver of documentation of consent. There are required elements that must be met, but a waiver of documentation of consent means that you will obtain consent, but you do not use an informed consent document.

Indicate the nature of this request	☒ waiver of authorization (complete I and III) ☐ alteration or waiver of consent (complete II.A, II.B & III) ☐ waiver of documentation of consent (complete II.A, II.C & III)
Does this research present no more than Minimal Risk of harm to subjects	☒ Yes; Explain: No PHI will be recorded for study purposes and all data in the external facing, NYU maintained, REDCap Registry will be de-identified and use unique study ID. A separate secure REDCap database will be used to link study IDs with PHI (name, date of birth, surgical date and MRN) for longitudinal tracking purposes. ☐ No; **STOP:** This study is not eligible for an Alteration or Waiver of Authorization or Consent or a Waiver of Documentation of Consent

I. Authorization

Fill this out if you seek to obtain a waiver of authorization to use and disclosures protected health information.

A. Record/Specimen Use

Check the boxes of the items that will be used

Indicate your study's source(s) of health information	☒ physician/clinic records ☒ interviews/questionnaires ☐ mental health records ☐ billing records	☒ lab, pathology and/or radiology results ☐ biological samples obtained from the subjects ☒ hospital/medical records (in- and out-patient) ☐ data previously collected for research purposes ☐ other; specify:

B. Protected Health Information

Describe the PHI being used or disclosed in your study	☐ Patient/subject name ☐ Address street location ☐ Address town or city ☐ Address state ☐ Address zip code ☐ Elements of dates (except year) related to an individual. (ie. DOB, admission/discharge dates, date of death) ☐ Telephone number ☐ Fax number ☐ Electronic mail (email) address ☐ Social security number ☐ Medical record numbers ☐ Health plan beneficiary numbers ☐ Account numbers ☐ Certificate/license numbers ☐ Vehicle identification numbers and serial numbers including license plates ☐ Medical device identifiers and serial numbers ☐ Web URLs ☐ Internet protocol (IP) address ☐ Biometric identifiers (finger and voice prints) ☐ Full face photographic images ☐ Any unique identifying number, characteristic or code (a rare disease can be considered a unique id) ☐ Link to identifier (code)

C. Request for Waiver of Authorization

If any box in section I.B above is checked, list every investigator, research staff member or other staff member who will have access to this data	Ran Schwarzkopf, MD – Principle Investigator James Feng, MD – Researcher Afshin Anoushiravani, MD – Researcher
Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy	This registry will encompass retrospective collection of data from patients undergoing standard care practices for joint replacement surgery. All data obtained will be placed securely on a REDCap server. PHI (including name, date of birth, date of surgery and MRN) will be used for the purpose of longitudinal tracking of patients using unique study IDs and stored on a separate secure, NYU REDCap registry for longitudinal tracking purposes. All data used in the implant registry will be deidentified.
Describe investigator's plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time	PHI will only be used to identify eligible subjects through unique study IDs and stored on a separate REDCap server. PHI will be discarded appropriately 2 years after the conclusion of the study in compliance with auditing purposes.
Explain why it is not possible to seek subjects' authorization for use or disclosure of the PHI	PHI is required for patient identification and longitudinal follow-up. Patients will not be contacted for this study, nor approached for consent. Patient contact and obtaining consent would increase the risk of a breach of confidentiality for this study.
Explain why it is not possible to conduct this research without use or disclosure of the PHI	PHI is required to identify potential subjects for this study.

II. Informed Consent

Complete II.A and II.B if you are seeking an alteration or complete waiver of your research subject's right to informed consent.

Complete II.A and II.C if you are seeking a waiver of documentation of informed consent.

A. Overview

Briefly explain the consent process for your study	

B. Alteration or Waiver of Informed Consent

Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject	
Explain why the waiver/alteration will not adversely affect the rights and welfare of the subjects	
Explain why it is impracticable to conduct this research if informed consent is required	
Explain, if appropriate, how the subjects will be provided with additional pertinent information after participation. If not appropriate, explain why	

C. Waiver of Documentation of Informed Consent

For this subsection, complete either Subsection 1 or 2

Subsection 1

(a) The only record linking the subject to the research will be the consent document	☐ Yes; explain: ☐ No; **not eligible for waiver under this section:**
(b) Would the principal risk would be potential harm resulting from a breach in confidentiality	☐ Yes; explain: ☐ No
(c) Will subjects be provided with a written statement regarding the research*	☐ Yes; Attach document for IRB Review and Approval ☐ No explain: Retrospectively obtained patients will have no interaction with the research staff.

**to proceed with a waiver meeting the above criteria, each subject must be asked whether they wish documentation linking them to your study. You must include this in your description of the consent process in II.A (above) and in your protocol.*

Subsection 2

(a) Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject	The registry is observational in nature and does not encompass any additional adverse events. The risks associated with our study are related to feelings of embarrassment, psychological discomfort, and/or self-consciousnesses regarding their disease state.
(b) The research involves no procedures for which written consent is normally required outside the research context	☐ Yes; explain:. All procedures performed in this study are part of standard patient care. ☐ No**; not eligible for waiver under this section**
(c) Will subjects be provided with a written statement regarding the research*	☐ Yes; Attach document for IRB Review and Approval ☒ No explain: Paitients will not be contacted by research personnel.

to proceed with a waiver meeting the above criteria, each subject must be asked whether they wish documentation linking them to your study. You must include this in your description of the consent process in II.A (above) and in your protocol.

III. Signatures

Principal Investigator's Signature

Date	11/1/2017
Print Name	Ran Schwarzkopf, MD
Signature	to sign

I assure the IRB that the protected health information which I have detailed in this Waiver of Authorization and/or Consent application will not be reused (i.e.: used other than as described in this application) or disclosed to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by the NYU SoM IRB.

I also assure the NYU SoM IRB that the information that I provide in this application is accurate and complete, and that the PHI that I request is the minimum amount of identifiable health information necessary for my research project.