

Approval of Submission

May 2, 2019

On 5/2/2019 the IRB reviewed and approved the following submission:

principal investigator	James Slover
study number	i12-02567_CR6
study title	Factors Influencing Patient Expectations in Joint Replacement Surgery
performance period	5/2/2019 - 5/1/2020
location(s)	Center for Musculoskeletal Care (NYUMC Locations), Other than listed (Other Locations), Hospital for Joint Diseases (NYUMC Locations)
sponsor(s)	Name: Orthopaedic Surgery
review type	Continuing Review [Expedited Cat 5,7]
board name	Report to all boards
materials approved for use	<ul style="list-style-type: none"> Expectations Protocol Modified_clean (3.14.14).pdf, Category: IRB Protocol <p>***This study is closed to new enrollment***</p>

The current IRB Status of your submission is: Approved. This submission was reviewed by the NYU School of Medicine's Institutional Review Board (IRB). During the review of your study, the IRB specifically considered:

1. the risks and anticipated benefits (if any) to your subjects
2. the selection of subjects
3. the procedures for securing and documenting informed consent
4. the safety of your subjects
5. the privacy of your subjects and confidentiality of the data

Your study cannot commence until all ancillary review decisions are complete. To determine the state of all ancillary reviews, go the MyStudies page of this study in Research Navigator. Ancillary review statuses are located on the top/right area of your study's main screen.

Note: Ensure that approval has been issued in MyAgreements/CRMS and the Clinical Research Support Unit ("CRSU") before you proceed with any aspect of this study, including the enrollment of human subjects.

Review Notes

For NIH grant funded research approved before the revised Common Rule: the IRB has found the IRB approved protocol referenced above to be consistent with the NIH grant application.

Sincerely,



5/2/2019

RE: Study# i12-02567

Helen Panageas

Director, NYU SoM Institutional Review Board

Federalwide Assurance: FWA00004952

NYU School of Medicine's IRB operates in accordance with Good Clinical Practices (GCP) and applicable laws and regulations. Federal rules allow IRBs to document their determination/authorization process in their policy manual. Determination letters generated by NYU SoM's IRB administration system are not physically signed as per policy. All approved study materials are clearly identified and locked in each study submission record within the IRB's administration system.

NYU School of Medicine IRB Policy

- All current IRB policy documents can be found on our [website](#)
- You must submit all modifications to this study (e.g., protocol updates, modified recruitment materials, consent forms, etc.) using Research Navigator to communicate with the IRB ("eSubmission") for review and approval prior to initiation of those change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
- All adverse and/or unanticipated event(s) that occur while conducting this study must immediately be reported to the IRB via eSubmission.
- You may only use IRB-approved copies of your consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your study. Never use expired consent forms.
- If modifications are made to the study or adverse events occur while conducting study, the PI must inform all research staff listed on this study.
- IRB's approval is valid as per the period indicated above. A reminder to submit a continuation (should one be required) will be e-mailed to the PI, PI Proxy and Primary Contact 90, 60 and 30 days prior to this study's expiration date if one is indicated. After expiration, a daily reminder will be sent for 30 days followed by a weekly reminder until the study receives re-approval or a study closure.
- Prior to initiating an IRB-approved study, you must receive written approval from an authorized representative for each site where your study will take place. Key contacts are:
 - Bellevue Hospital (BHC): if you are conducting all or part of your study at BHC, you must contact them to obtain additional approvals. BHC will be notified if any of their sites are selected as a location where your study takes place, but your team is obligated to contact them at BellevueResearch@bellevue.nychhc.org to find out what approvals are required before conducting any research at a BHC location.
 - CTSI - Clinical and Translational Science Institute, NYU School of Medicine [formerly General Clinical Research Center (GCRC)]: email ctsi@nyulangone.org
 - NYU Langone Health Centers (Tisch Hospital/Rusk Institute/Co-op Care/HJD/Perlmutter Cancer Center) site approval is handled for you automatically (as needed) by the CRSU
- The IRB may suspend or terminate studies that are not in compliance with NYU Langone Health/School of Medicine Policies & Procedures and the requirements of the Institution's Federal Wide Assurance with the federal government.
- Direct IRB questions and comments to 212-263-4110 or IRB-INFO@nyulangone.org

[Let Us Know How We're Doing](#)

Click on the title above to send us feedback via a short, anonymous survey. Providing exceptional customer service is a top priority of the IRB and your responses will help us understand how we can continue to improve our service to the research community.

IRB Board Rosters

Effective **2019-03-04** FWA#00004952

Quorum is simple majority only = greater than half

Board A (Effective 2019-03-04)

Members; Quorum of 7; 8 for prisoner-related studies

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
More, Frederick (Chair)	DDS	S	Dentistry – Pediatrics	Y	Hazen, Katz, Nishawala, Novik, Wissner-Greene
Bliss, Samuel	PharmD	S	Pharmacy	Y	Ballani, Dubrobskaya, Faiena, Wong
Diefenbach, Catherine	MD	S	Oncology	Y	Esteva, Kwa, Novik, Rapp, Ryan, Schiff, Wu
Donnino, Robert	MD	S	Medicine – Cardiology	Y	Culliford, Katz
Gallagher, Richard	PhD	S	Child & Adolescent Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, McGregor, Nishawala, Rotrosen
Godina, Marina	RN	S	IRB Administration; Nursing	Y	Berkovitz, Jeschke-Lopez, Johnson
Kadidal, Shane *	JD	NS	Law – Prisoner Advocate	N	
Lamont, Justin	MD	S	Orthopedic Surgery	Y	Kirsch, Leucht, Rapp
Panageas, Helen	BA	NS	IRB Administration	Y	Dvorkin, Liu, McGowan, Vieira, Wallach
Raskin, Joyce	JD	NS	Community Representative	Y	Abramovitz
Ross-Rizzo, John	MD	S	Neurology	Y	Barr, Berk, Chervinsky, Lewis
Ross, Stephen	MD	S	Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, McGregor, Nishawala, Rotrosen
Storey, Elizabeth	PhD	S	Radiology	Y	Bencardino, Fieremans, Friedman, Gonen
Wang, Jing	MD	S	Anesthesiology	Y	Kim

Counts toward quorum only when reviewing studies subject to Subpart C

Board B (Effective 2019-03-04)**Members; Quorum of 9, 9 for prisoner-related studies**

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
Katz, Stuart (Chairman)	MD PhD	S	Cardiology	Y	Hazen, More, Nishawala, Novik, Wissner-Greene
Hazen, Alexes (Vice Chair)	MD	S	Surgery – Plastic	Y	Vice Chair Alternates: More, Nishawala, Novik, Wissner-Greene Member Alternates: DeLacure
Berk, Thomas	MD	S	Neurology	Y	Barr, Lewis, Ross-Rizzo
Brar, Preneet	MD	S	Pediatric Endocrinology	Y	Ramirez, Tunik, Wissner-Greene
Chervinsky, Alexander B	PhD	S	Neuropsychology	Y	Barr, Bogenschutz, Gallagher, Lewis, McGregor, Nishawala, Ross, Rotrosen
Culliford, Alfred	MD	S	Surgery – Cardiothoracic	Y	Donnino, Lamont, Rapp
Dubrovskaya, Yanina	PharmD	S	Pharmacy	Y	Ballani, Bliss, Faiena, Wong
Esteva, Francisco	MD	S	Oncology	Y	Diefenbach, Novik, Rapp, Ryan, Schiff, Wu
Fieremans, Els	PhD	S	Radiology	Y	Bencardino, Friedman, Gonen, Storey
Frankle, William Gordon	MD	S	Psychiatry	Y	Barr, Bogenschutz, Gallagher, McGregor, Nishawala, Ross, Rotrosen
Godina, Marina	RN	S	IRB Administration; Nursing	Y	Berkovitz, Jeschke-Lopez Johnson
Kadidal, Shane *	JD	NS	Law-Prisoner Advocate	N	
Kirsch, Thorsten	PhD	S	Orthopedic Surgery	Y	Lamont, Leucht, Rapp
Kwa, Maryann	MD	S	Oncology	Y	Diefenbach, Novik, Rapp, Ryan, Schiff, Wu
McGowan, Richard	MLS	NS	Public Services	Y	Vieira
Nolan, Anna	MD	S	Pulmonary	Y	
Panageas, Helen	BA	NS	IRB Administration	Y	Dvorkin, Liu, Vieira, Wallach
Raskin, Joyce	JD	NS	Community Representative	Y	Abramovitz

*Counts toward quorum only when reviewing studies subject to Subpart C

Board C (Effective 2019-03-04)**Members; Quorum of 6; 7 for prisoner-related studies**

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
Novik, Yelena (Chair)	MD	S	Oncology	Y	Hazen, Katz, More, Nishawala, Wissner-Greene
Nishawala, Melissa (Vice Chair)	MD	S	Child & Adolescent Psychiatry	Y	Vice Chair Alternates: Hazen, Katz, More, Wissner-Greene Member Alternates: Barr, Bogenschutz, Chervinsky, Frankle, Gallagher, McGregor, Ross, Rotrosen
Godina, Marina	RN	S	IRB Administration; Nursing	Y	Berkovitz, Jeschke-Lopez, Johnson
Kadidal, Shane *	JD	NS	Law – Prisoner Advocate	N	
Kim, Sunmi	MD	S	Anesthesiology	Y	Wang
Lewis, Ariane	MD	S	Neurocritical Care	Y	Barr, Berk, Ross-Rizzo
Panageas, Helen	BA	NS	IRB Administration	Y	Dvorkin, Liu, McGowan, Wallach
Raskin, Joyce	JD	NS	Community Representative	Y	Abramovitz
Schiff, Peter	MD	S	Radiation Oncology	Y	Diefenbach, Esteva, Kwa, Ryan
Vieira, Dorice	MA	NS	Public Services	Y	McGowan
Wong, Doris	PharmD	S	Pharmacy	Y	Ballani, Bliss, Dubrovskaya, Faiena
Wu, Jennifer	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Ryan

*Counts toward quorum only when reviewing studies subject to Subpart C

Board D (Effective 2019-03-04)**Members; Quorum of 8; 9 for prisoner-related studies**

Member	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate(s)
More, Frederick (Chair)	DDS	S	Dentistry – Pediatrics	Y	Hazen, Katz, Nishawala, Novik, Wissner-Greene
Wissner-Greene, Loren (Vice Chair)	MD, MA	S	Medicine – Endocrinology – Ob-Gyn	Y	Vice Chair Alternates: Hazen, Katz, More, Nishawala, Novik, Member Alternate: Brar
Abramovitz, Rachel	LL.M., LL.B.	NS	Community Representative	N	Raskin
Ballani, Kanika	PharmD	S	Pharmacy	Y	Bliss, Dubrovskaya, Faiena, Wong
Barr, William	PhD	S	Neuropsychology	Y	Berk, Chervinsky, Frankle, Gallagher, Lewis, McGregor, Nishawala, Ross, Ross-Rizzo, Rotrosen,
Bogenschutz, Michael	MD	S	Psychiatry	Y	Chervinsky, Frankle, Gallagher, McGregor, Nishawala, Ross, Rotrosen
Dedania, Vaidehi	MD	S	Ophthalmology	Y	
Godina, Marina	RN	S	IRB Administration; Nursing	Y	Berkovitz, Jeschke-Lopez, Johnson
Gonen, Oded	PhD	S	Radiology	Y	Bencardino, Fieremans, Friedman, Storey
Kadidal, Shane *	JD	NS	Legal – Prisoner Advocate	N	
Leucht, Philipp	MD, PhD	S	Orthopaedic Trauma	Y	Kirsch, Lamont, Rapp
Mehta-Lee, Shilpi	MD	S	Ob-Gyn	Y	
Mola, Ana	PhD, RN	S	Nursing	Y	Dugan
Panageas, Helen		NS	IRB Administration	Y	Dvorkin, Liu, McGowan, Vieira, Wallach
Ramirez, Michelle	MD	S	Pediatric Critical Care	Y	Brar, McGregpr, Oshva, Tunik
Ryan, Theresa	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Novik, Rapp, Schiff, Wu

*Counts toward quorum only when reviewing studies subject to Subpart C

Board E (Effective 2019-03-04)**Members; Quorum of 4; 4 for prisoner-related studies**

Member	Degree(s)	Science – Non- Science	Specialty	Affiliated With NYU	Alternate(s)
More, Frederick (Chair)	DDS	S	Dentistry	Y	Hazen, Katz, Nishawala, Novik, Wissner-Greene
Katz, Stuart (Vice-Chair)	MD	S	Cardiology	Y	Vice Chair Alternates: Hazen, More, Nishawala, Novik, Wissner-Greene Member Alternates: Culliford, Donnino
Johnson, Nadia	MS	S	IRB Administration	Y	Berkovitz, Godina, Jeschke-Lopez
Wu, Jennifer	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Novik, Rapp, Ryan, Schiff
Kadidal, Shane *	JD	NS	Law-Prisoner Advocate	N	
Panageas, Helen		NS	IRB Administration	Y	Dvorkin, Liu, McGowan, Vieira, Wallach
Raskin, Joyce	JD	NS	Community Representative	Y	Abramovitz

*Counts toward quorum only when reviewing studies subject to Subpart C

Alternates

Alternate	Degree(s)	Science – Non-Science	Specialty	Affiliated With NYU	Alternate For
Abramovitz, Rachel	LL.M., LL.B.	NS	Community Representative	N	Raskin
Ballani, Kanika	PharmD	S	Pharmacy	Y	Bliss, Dubrovskaya, Wong
Barr, William	PhD	S	Neuropsychology	Y	Berk, Chevinsky, Frankle, Gallagher, Lewis, Nishawala, Ross, Ross-Rizzo
Bencardino, Jenny	MD	S	Radiology	Y	Fieremans, Gonen, Schiff
Berk, Thomas	MD	S	Neurology	Y	Barr, Lewis, Ross-Rizzo
Berkovitz, David	MD	S	IRB Administration	Y	Godina
Bliss, Samuel	PharmD	S	Pharmacy	Y	Ballani, Dubrovskaya, Wong
Bogenschutz, Michael	MD	S	Psychiatry	Y	Barr, Chervinsky, Frankle, Gallagher, Nishawala, Ross
Brar, Preneet	MD	S	Pediatric Endocrinology	Y	Ramirez, Wissner-Greene
Chervinsky, Alexander	PhD	S	Neuropsychology	Y	Barr, Bogenschutz, Gallagher, Nishawala, Ross, Ross-Rizzo
Culliford, Alfred	MD	S	Surgery – Cardiothoracic	Y	Donnino, Katz
DeLacure, Mark D	MD	S	Otolaryngology & Plastic Surgery	Y	Hazen
Diefenbach, Catherine	MD	S	Oncology	Y	Esteva, Kwa, Ryan, Schiff, Wu
Donnino, Robert	MD	S	Medicine – Cardiology	Y	Culliford
Dubrovskaya, Yanina	PharmD	S	Pharmacy	Y	Ballani, Bliss, Wong
Dugan, Christina	RN	S	Medicine	Y	Mola
Dvorkin, Ella		NS	IRB Administration	Y	Panageas
Esteva, Francisco	MD	S	Oncology	Y	Diefenbach, Kwa, Ryan, Schiff, Wu
Faiena, Mark	PharmD	S	Pharmacy	Y	Ballani, Bliss, Dubrovskaya, Wong
Fieremans, Els	PhD	S	Radiology	Y	Gonen, Storey
Frankle, William Gordon	MD	S	Psychiatry	Y	Barr, Bogenschutz, Gallagher, Nishawala, Ross
Friedman, Kent	MD	S	Radiology	Y	Fieremans, Gonen, Storey
Gallagher, Richard	PhD	S	Child & Adolescent Psychiatry	Y	Chervinsky, Frankle, Nishawala, Ross
Gonen, Oded	PhD	S	Radiology	Y	Fieremans, Storey
Hazen, Alexes	MD	S	Plastic Surgery	Y	Katz, More, Nishawala, Novik, Wissner-Greene
Jeschke-Lopez, Ikoa	MD	S	IRB Administration	Y	Godina
Johnson, Nadia	MS	S	IRB Administration	Y	Godina
Katz, Stuart	MD	S	Cardiology	Y	Donnino, Hazen, More, Nishawala, Novik, Wissner-Greene
Kim, Sunmi	MD	S	Anesthesiology	Y	Wang
Kirsch, Thorsten	MD	S	Orthopedic Surgery	Y	Lamont, Leucht, Rapp
Kwa, Maryann	MD	S	Oncology	Y	Diefenbach, Novik, Ryan, Schiff, Wu
Lamont, Justin	MD	S	Orthopedic Surgery	Y	Culliford, Hazen, Kirsch, Leucht, Rapp
Leucht, Philipp	MD, PhD	S	Orthopaedic Trauma	Y	Kirsch, Lamont, Schiff
Liu, Jasmine	BS	NS	IRB Administration	Y	Panageas
Lewis, Ariane	MD	S	Neurocritical Care	Y	Barr, Berk, Ross-Rizzo
McGowan, Richard	MLS	NS	Public Services	Y	Panageas, Vieira

McGregor, Kyle	PhD	S	Child & Adolescent Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, Gallagher, Nishawala, Ross
Mola, Ana	PhD, RN	S	Nursing	Y	
More, Frederick	DDS	S	Dentistry – Pediatric	Y	Hazen, Katz, Nishawala, Novik, Wissner-Greene
Nishawala, Melissa	MD	S	Child & Adolescent Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, Hazen, Katz, More, Novik, Ross, Wissner-Greene
Nolan, Anna	MD	S	Pulmonary	Y	
Novik, Yelena	MD	S	Oncology	Y	Diefenbach, Esteva, Katz, Kwa, Hazen, More, Nishawala, Ryan, Wissner-Greene, Wu
Oshva, Lillian	MD	S	Emergency Medicine	Y	Ramirez
Ramirez, Michelle	MD	S	Pediatric Critical Care	Y	Brar
Rapp, Timothy	MD	S	Orthopedic Surgery – Oncology	Y	Culliford, Diefenbach, Esteva, Kirsch, Kwa, Lamont, Leucht, Ryan, Schiff, Wu
Raskin, Joyce	JD	NS	Community Representative	Y	Abramovitz
Ross, Stephen	MD	S	Addiction Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, Nishawala
Ross-Rizzo, John	MD	S	Neurology	Y	Barr, Chervinsky, Lewis,
Rotrosen, John	MD	S	Psychiatry	Y	Barr, Bogenschutz, Chervinsky, Frankle, Gallagher, Nishawala, Ross
Ryan, Theresa	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Novik, Ryan, Schiff, Wu
Schiff, Peter	MD	S	Radiation – Oncology	Y	Diefenbach, Esteva, Kwa, Ryan, Wu
Storey, Elizabeth	PhD	S	Radiation	Y	Fieremans, Gonen
Tunik, Michael	MD	S	Pediatric EM	Y	Brar, More, Ramirez
Vieira, Dorice	MA	NS	Public Services	Y	McGowan, Panageas
Wallach, David	BA, MPH	NS	IRB Administration	Y	Panageas
Wang, Jing	MD	S	Anesthesiology	Y	Kim
Wissner-Greene, Loren	MD, MA	S	Medicine – Endocrinology – Ob-Gyn	Y	Brar, Hazen, Katz, More, Nishawala, Novik,
Wong, Doris	PharmD	S	Pharmacy	Y	Ballani, Bliss, Dubrovskaya,
Wu, Jennifer	MD	S	Oncology	Y	Diefenbach, Esteva, Kwa, Ryan



DATE: 13-Mar-2019
TO: Charles L Nelson
CC: Dooley, Mary E
Horan, Annamarie D
Moses, Helena T

Institutional Review Board
3800 Spruce St., First Floor Suite 151
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

RE:
IRB PROTOCOL#: 818814
PROTOCOL TITLE: Factors influencing patient expectations in joint replacement surgery

SPONSOR: NO SPONSOR NUMBER
REVIEW BOARD: IRB #7

IRB CONTINUING REVIEW: NOTICE OF APPROVAL

Dear Dr. Nelson,

The above referenced protocol was reviewed and re-approved by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 on 12-Mar-2019. This study has been determined to be eligible for expedited review category(ies) 5,7.

Consistent with the regulations set forth in 45 CFR 46.109(f), continuing review of this research is not required. IRB approval of this protocol will not expire and continuing review applications should not be submitted. However, you are still required to submit modifications and reportable events to the IRB for review.

The documents included with the application noted below are approved:

-HS-ERA Continuing Review Submission (Confirmation Code: ciabjehb), submitted on 03/09/2019

ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: <http://www.irb.upenn.edu>

This letter constitutes official University of Pennsylvania IRB correspondence.