

**AWARD NUMBER:** W81XWH-17-1-0665

**TITLE:** Prevention of Post-Traumatic Contractures with Ketotifen II (PERK 2)

**PRINCIPAL INVESTIGATOR:** Kevin A. Hildebrand

**CONTRACTING ORGANIZATION:** University of Calgary, Calgary, Alberta, Canada

**REPORT DATE:** October 2021

**TYPE OF REPORT:** Annual Report

**PREPARED FOR:** U.S. Army Medical Research and Development Command  
Fort Detrick, Maryland 21702-5012

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<b>1. REPORT DATE</b> October 2021		<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 30Sep2020-29Sep2021
<b>4. TITLE AND SUBTITLE</b> Prevention of Posttraumatic Contractures with Ketotifen II (PERK2)			<b>5a. CONTRACT NUMBER</b> W81XWH-17-1-0665	
			<b>5b. GRANT NUMBER</b> OR160026	
			<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Kevin A. Hildebrand  E-Mail: hildebrk@ucalgary.ca			<b>5d. PROJECT NUMBER</b>	
			<b>5e. TASK NUMBER</b>	
			<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> Governors of the University of Calgary 2500 University Drive NW Calgary, Alberta CANADA T2N 1N4			<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012			<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
			<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
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<b>13. SUPPLEMENTARY NOTES</b>				
<b>14. ABSTRACT</b> Regulatory approvals - US Food and Drug Administration, USAMRMC Human Research Protections Office (HRPO), Health Canada - have been completed for 15 participating sites. 16 of the participating sites have received ethics approval. Site initiation visits were completed at 2 sites, with 15 actively recruiting. Bay Area Research Logistics (BARL) has completed shipment of medication to 15 sites, with plans on shipping medication to 1 more site during Q1 of year 5. These efforts have led to active sites successfully recruiting and randomizing 161 participants. Site contract negotiations have been completed for all 17 sites. Bi-weekly safety summary meetings are being held with local Research Monitor to review AE/SAE's. Updated versions of charters for Data Monitoring Committee (DMC), Trial Steering Committee (TSC), and Trial Management Group (TMG) were finalized. Monthly TMG meetings are being held, with TSC meetings occurring every three months. DMC membership has been finalized, and an introductory meeting held with stakeholders. First DMC meeting is scheduled to occur during Year 5, Q1. A 1 year No Cost Extension was granted by U.S. Army Medical Research and Development Command to continue enrollment and follow up procedures for the trial.				
<b>15. SUBJECT TERMS</b> Randomized Clinical Trial; Multicenter; Placebo; Ketotifen; Contractures; Post-traumatic; Elbow fractures or dislocations; Surgery; Range of motion; Disability Arm Shoulder Hand; Oxford Elbow Score; Pain Catastrophizing Scale.				
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  Unclassified	<b>18. NUMBER OF PAGES</b>
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				<b>19b. TELEPHONE NUMBER (include area code)</b>

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## 1. INTRODUCTION:

This proposal pertains to the FY16 PRORP CTA Focus Area on Surgical Care – Extremity Fractures. This research optimizes patient outcomes through prevention of post-traumatic joint contractures following fractures. We are conducting a multicenter, multidose randomized clinical trial comparing Ketotifen fumarate to a Lactose placebo started within 7 days of elbow fractures or dislocations. The primary outcome measure is elbow extension-flexion arc range of motion 12 weeks after randomization. Secondary outcome measures are range of motion at other selected time points and patient reported outcome measures at these time points and 12 weeks.

## 2. KEYWORDS:

Randomized Clinical Trial; Multicenter; Placebo; Ketotifen; Contractures; Post-traumatic; Elbow fractures or dislocations; Surgery; Range of motion; Disability Arm Shoulder Hand; Oxford Elbow Score; Pain Catastrophizing Scale

## 3. ACCOMPLISHMENTS:

### What were the major goals of the project?

Major Task 1: Complete Clinical Trial Development Award – this was OR140142

Major Task 2: Phase III RCT Implementation

Major Task 3: Study Performance

Major Task 4: Knowledge Translation

### What was accomplished under these goals?

Major Task 1: Complete CTDA OR140142

1. Major Activities:

- a. Regulatory Compliance
- b. Core Study Functions
- c. Recruiting Sites

2. Specific Objectives:

- a. Complete contract negotiations with recruiting sites.
- b. Obtain Ethics Internal Review Board and Department of Defense Human Research Protection Office (HRPO) approval for 17 participating sites.

3. Results:

- a. Contracts completed and signed off for the following sites. **See appendices pages 15 – 16:**
  - i. Royal Columbian Hospital
- b. Ethic board approvals were received for the following sites. **See appendices pages 17 – 20:**
  - i. McGill University
  - ii. Royal Columbian Hospital
- c. Human Research Protection Office (HRPO) submission approvals were received for the following sites. **See appendices pages 21 – 28:**
  - i. Royal Columbian Hospital
  - ii. McGill University
- d. Initial Investigational Product shipments completed through BARL to the following sites. **See appendices pages 29 – 32:**
  - i. Carolinas Medical Center
  - ii. Sunnybrook Health Science Center
  - iii. Queen Elizabeth II Health Science Center
  - iv. Royal Columbian Hospital

## Major Task 2: Phase III RCT Implementation

1. Major Activities:
  - a. Organizational Transitions
  - b. Site Initiations
  - c. Organizing Screening, Enrollment and Randomization Procedures
2. Specific Objectives:
  - a. Start at Calgary Sites
  - b. Site roll out outside of Calgary
3. Results:
  - a. Site initiation visits completed at the following sites. **See appendices pages 33 – 35:**
    - i. Royal Columbian Hospital
    - ii. Queen Elizabeth II Health Science Center
  - b. Following site initiation visits, official enrolment and randomization procedures started at 15 sites. As a result, 161 participants have been recruited and randomized into the clinical trial. Appendix reflects 161 participants randomized by the end of the reporting period. **See appendices page 36 – 40.**

### Major Task 3: Study Performance

1. Major Activities:
  - a. Trial Committees
  - b. Support Organizations
2. Specific Objectives:
  - a. Three performance committees meetings
  - b. Regular meetings with Core facilities – EPICORE, CIPAC, BARL
3. Results:
  - a. Monthly Trial Management Group (TMG) meetings were held during this reporting period. **See appendices pages 41 - 49.**
  - b. Trial Steering Committee (TSC) meetings were held during this reporting period. **See appendices pages 50 – 52.**
  - c. Data Monitoring Committee introductory meeting held. **See appendices pages 53 – 56.**

### Major Task 4: Knowledge Translation

1. Major Activities:
  - a. Publications/Meetings
  - b. Trial Results
  - c. Site Engagement and Updates
2. Specific Objectives
  - a. Trial protocol manuscript, Specialty meetings abstracts and attendance
  - b. Trial results – Primary paper, secondary papers, presentations specialty societies
  - c. Site engagement
3. Results
  - a. Monthly PERK 2 newsletter continued through the year. **See appendices pages 57 – 59.**

**What opportunities for training and professional development has the project provided?**

Our trial coordinator, Gerardo Duque, and trial assistant, Taylor Stranaghan, completed the “Leadership in Patient-Oriented Research: Pragmatic Clinical Trials Certificate” provided by the Alberta SPOR Support Unit. This is a recognized certification supporting the development and excellence of active clinical trial staff. **See appendices page 60.**

**How were the results disseminated to communities of interest?**

Nothing to report.

**What do you plan to do during the next reporting period to accomplish the goals?**

The main objectives for the year are to continue enrollment and randomization procedures with 16 active sites. In regards to regulatory compliance leading to site start-ups, our objective is to complete all procedures involved for the 1 remaining site by Year 5, Quarter 1. Continuing the TMG and TSC meeting, and running the first DMC meeting during Year 5, Quarter 1. Regular meetings with the support organizations CIPAC, BARL, and EPICORE. Finally, continuing manuscript and presentation development, with eyes set in further literature development efforts towards Year 5, Quarter 2.

**4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report.

**What was the impact on other disciplines?**

Nothing to Report

**What was the impact on technology transfer?**

Nothing to Report

**What was the impact on society beyond science and technology?**

Nothing to Report

**5. CHANGES/PROBLEMS:**

**Changes in approach and reasons for change**

No foreseeable changes in approach are expected. Following all protocol changes done during Year 4 to address COVID-19 limitations, sites are able to engage in trial tasks and procedures consistently.

**Actual or anticipated problems or delays and actions or plans to resolve them**

COVID-19 restrictions and limitation on research lead to significant delays in restarting sites during Year 4. However, we will begin Year 5 with 15 sites enrolling/randomizing, with one more site joining the team early in Q1. Recruitment was significantly affected by COVID-19, but we are working towards maintaining our current momentum, reaching 16 new recruitments per month.

**Changes that had a significant impact on expenditures**

Nothing to report

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

Nothing to report

**Significant changes in use or care of human subjects**

Nothing to report

**Significant changes in use or care of vertebrate animals**

Nothing to report

**Significant changes in use of biohazards and/or select agents**

Nothing to report

**6. PRODUCTS**

- **Publications, conference papers, and presentations**

**Journal publications.**

Nothing to report

**Books or other non-periodical, one-time publications.**

Nothing to report

**Other publications, conference papers and presentations.**

Nothing to report

- **Website(s) or other Internet site(s)**

Nothing to report

- **Technologies or techniques**

Nothing to report

- **Inventions, patent applications, and/or licenses**

Nothing to report

- **Other Products**

Nothing to report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Name: Kevin Hildebrand  
Project Role: Principal Investigator  
Research Identifier: orcid.org/0000-0001-8786-9021  
Nearest Person Month worked: 12  
Contribution to Project: Overall management. Writing grants, study design. Recruiting sites. Obtaining data management, medication partners.  
Funding Support: Department of Surgery University of Calgary

Name: Gerardo Duque  
Project Role: Research Coordinator  
Research Identifier: None  
Nearest Person Month worked: 12  
Contribution to Project: Regulatory application (IND, HRPO, Health Canada). Database Development and quality assurance. Case report forms and consent writing. Screening, recruitment, randomization, and participant follow-ups. Contracts. Institutional Review Board processing.  
Funding Support: Department of Defense.

Name: Taylor Stranaghan  
Project Role: Clinical Research Assistant  
Research Identifier: None  
Nearest Person Month Worked: 6  
Contribution to Project: Clinical trial implementation and ongoing development. Screening, recruitment, randomization, and participant follow-ups. Case report form development. Institutional Review Board processing.  
Funding Support: Department of Defense

Funding Support:	Department of Defense
Name:	Tolulope Sajobi
Project Role:	Trial Statistician
Research Identifier:	orcid.org/0000-0002-5696-5552
Nearest Person Month worked:	1
Contribution to Project:	Statistical support. Recruitment and co-supervise PhD student.
Funding Support:	Department of Community Health Sciences, University of Calgary
Name:	Ayoola Ademola
Project Role:	PhD Graduate Student
Research Identifier:	None
Nearest Person Month worked:	1
Contribution to Project:	Statistical support
Funding Support:	Department of Defense

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to report

**What other organizations were involved as partners?**

Organization Name:	Bay Area Research Logistics
Location:	Hamilton, ON, CANADA
Contribution:	Sourcing Ketotifen, Lactose Placebo, manufacturing and distribution study medication
Organization Name:	EPICORE Centre
Location:	University of Alberta, Edmonton, AB, CANADA
Contribution:	Development of RedCap Electronic Data Capture, Randomization process (Drug Tracking System), Project management, servers to support study
Organization Name:	Calgary Image Processing and Analysis Centre
Location:	Calgary, AB, CANADA
Contribution:	Archiving and analysis centre for radiographic evaluation of fracture healing
Organization Name:	Alberta Health Services
Location:	Peter Lougheed Centre, Calgary, AB, CANADA
Contribution:	Office space, computer support, clinic space for recruitment and follow up of participants

**8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:**

**QUAD CHARTS:** See appendices page 14.

**9. APPENDICES:**

# Prevention of Post-Traumatic Contractures with Ketotifen II (PERK II)

OR160026

W81XWH-17-1-0665



PI: Kevin A. Hildebrand

Org: Governors of the University of Calgary

Award Amount: \$2,440,796

## Study/Product Aim(s)

- Major Task 1: Complete Clinical Trial Development Award – CTDA (OR140142)
- Major Task 2: Phase III RCT Implementation
- Major Task 3: Study Performance
- Major task 4: Knowledge Translation

## Approach

PERK II is a multicenter RCT led from Calgary, CANADA with US centers included. Completing the CTDA will have the infrastructure in place to perform the RCT. This trial will compare 2 different doses of ketotifen fumarate to a lactose placebo in preventing post-traumatic contractures following elbow injuries that require an operation. The medication is randomized, while operation requirement is not.



161 participants recruited by last week of September. There are currently 15 sites able to screen/recruit participants. One more sites currently finalizing site initiation procedures to screen/recruit during Q1 of Year 5.

## Timeline and Cost

Activities	CY	17	18	19	20	21
Complete CTDA		█				█
Phase III RCT Implementation				█		
Study Performance				█		█
Knowledge translation				█		█
<b>Estimated Budget (\$K)</b>		<b>\$154</b>	<b>\$638</b>	<b>\$704</b>	<b>\$536</b>	<b>\$408</b>

## Goals/Milestones

**CY17 Goal** – Complete CTDA

- IND Approval
- ✓ Database and Medication Manufacture Development

**CY18 Goals** – Regulatory/IRB/Contracts

- ✓ PLC completed all steps
- ✓ Other sites in progress

**CY19 Goal** – Continue recruitment

- Complete CTDA
- ✓ Recruit first participant
- ✓ Add other sites

**CY20 Goal** – Continue recruitment, follow up

- All sites recruiting

## Comments/Challenges/Issues/Concerns

1 year no cost extension granted to continue enrollment and follow ups on year 5. 15/17 sites currently screening/recruiting.

## Budget Expenditure to Date

Projected Expenditure: \$2,440,795

Actual Expenditure: \$920,540

## **SUB-SITE AGREEMENT**

This Agreement is made and entered into as of the last date of signature by all parties (“Effective Date”).

AMONGST:

**Dr. Kevin Hildebrand** of Calgary, Alberta  
(the “PRINCIPAL INVESTIGATOR”)

OF THE FIRST PART,

- and -

**The Governors of the University of Calgary**  
2500 University Drive NW, Calgary, Alberta, Canada, T2N 1N4  
(the “PRINCIPAL INSTITUTION”)

OF THE SECOND PART,

-and-

**Dr. Farhad Moola**  
#403 233 Nelson’s Crescent, New Westminster, British Columbia, Canada V3L 0E4  
(the “SUB INVESTIGATOR”)

OF THE THIRD PART,

-and-


**Fraser Health Authority**  
#400 13450 102<sup>nd</sup> Avenue, Surrey, British Columbia, Canada V3T 0H1  
(the “SUB INSTITUTION”)

OF THE FOURTH PART

(The PRINCIPAL INVESTIGATOR, PRINCIPAL INSTITUTION, SUB INVESTIGATOR and SUB INSTITUTION may collectively be referred to as “Parties” and individually as a “Party”.)

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.


**PRINCIPAL INVESTIGATOR:**

Signature:  \_\_\_\_\_ Date December 16, 2020

Dr. Kevin Hildebrand


**PRINCIPAL INSTITUTION:**

**THE GOVERNORS OF THE UNIVERSITY OF CALGARY**

Per:  Exner for \_\_\_\_\_ Date 14 / Dec / 2020


Marcello Tonelli  
Senior Associate Dean, Health Research

**SUB INVESTIGATOR:**

Signature:  \_\_\_\_\_ Date 3 December 2020

Farhad Moola, MD FRCS

**SUB INSTITUTION:**

Authorized Signatures:  \_\_\_\_\_ Date December 3, 2020

Tracy Irwin  
Executive Director, Innovation, Research and Transformation



**CERTIFICATE OF FHREB APPROVAL**

<b>FHREB Number: 2020-002</b>			
<b>Principal Investigator:</b> MOOLA, Farhad		<b>Hospital/Facility &amp; Department:</b> RCH/Surgery	
<b>Institution(s) or Geographical Areas where research will be carried out:</b> RCH; ERH; Physician's Private Office			
<b>Co-Investigator(s):</b> PEREY, Bertrand; LEMKE, H. Michael; APOSTLE, Kelly; BOYER, Dory; VISKONTAS, Darius; STONE, Trevor			
<b>Funding Agencies and/or Corporate Sponsor:</b> United States of America Department of Defense			
<b>Title:</b> PreEvention of posttraumatic contractuRes with Ketotifen 2			
<b>Documents Included in this Approval</b>	<b>Date of Approval</b>	<b>Date of Expiry</b>	<b>Type of Approval</b>
<ul style="list-style-type: none"> <li>• Application for Initial Ethical Review</li> <li>• Appendix to Application, 2020 January 09</li> <li>• Researcher Response Form, 2020 March 17</li> <li>• Protocol Version 5.0, 2019 October 04</li> <li>• Health Canada No Objection Letter, 2018 August 09</li> <li>• Product Monograph Zaditen (Ketotifen fumarate), 2012 August 15</li> <li>• Investigator's Brochure Zadieten (Ketotifen fumarate) Edition 2.0, 2019 September 17</li> <li>• Consent Form Version 1.1, 2020 February 20</li> <li>• Wallet Card Version 2.1, 2020 February 20</li> <li>• Patient Demographics Version 1.0, 2019 July 25</li> <li>• PERK2 Participant Questionnaires Version 3.0, 2020 January 09</li> <li>• Participant Medications &amp; Study Drug Diary Version 2.0, 2019 July 09</li> <li>• PERK2 CRFs Version 2.0, 2019 October 15</li> <li>• PERK2 Drug Information Sheet Version 2.0, 2020 01 09</li> </ul>	2020 April 22	2021 April 22	Initial Approval; Full Board Review

**CERTIFICATION:**

**With respect to clinical trials:**

1. The membership of the Fraser Health Research Ethics Board complies with the membership requirements for research ethics boards as defined in Part C Division 5 of the Food and Drug Regulations and the Tri-Council Policy Statement.
2. The Fraser Health Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices.
3. The Fraser Health Research Ethics Board has reviewed and approved the clinical trial protocol and the informed consent form for the trial which is to be conducted by a qualified investigator named at the specified clinical trial site. This approval of the documentation listed above and the views of the Fraser Health Research Ethics Board have been documented in writing.

**With respect to delegated review:**

A co-chair or delegated member of the FHREB has reviewed and approved the documentation listed above for the forenamed research study in accordance with the FHREB Policy on Ethical Conduct of Research and Other Studies Involving Human Participants, the Tri-council Policy Statement: Ethical Conduct for Research Involving Humans, and the International Conference on Harmonisation Guidance E6: Good Clinical Practice E6: Consolidated Guidelines.

**With respect to full board review:**

Full FHREB review and approval of the documentation listed above was completed for non-expedited review in accordance with the FHREB Policy on Ethical Conduct of Research and Other Studies Involving Human Participants, the Tri-council Policy Statement: Ethical Conduct for Research Involving Humans and the International Conference on Harmonisation Guidance E6: Good Clinical Practice E6: Consolidated Guidelines.



4/22/2020

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**Certification by one of  
Dr. Stephen Pearce or Dr. Lindsay Meredith  
Co-Chairs, FHREB**

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**DATE OF SIGNATURE**

**The FHREB approval for this study expires ONE year from the approval date of this certificate. Researchers must submit a Request for Annual Renewal for ongoing research studies prior to the expiry date in order to receive annual re-approval.**



2021-03-03

Dr. Edward J. Harvey

c/o: Mary Amedeo

email: mary.amedeo@muhc.mcgill.ca

**Re: Final REB Approval of a New Research Project (PERK 2 / 2020-5501)**

"Prevention of Post-traumatic Contractures with Ketotifen 2"

**MUHC REB Co-Chair for the Clinical Trials 2 (CT2) Panel: Renaud Boulanger**

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Dear Dr. Harvey,

Thank you for submitting your responses and corrections for the research project indicated above, as requested by the McGill University Health Centre (MUHC) Research Ethics Board (REB).

The MUHC REB, more precisely its CT2 Panel provided conditional approval for the research project at its full board meeting of 2020-04-24.

On 2021-03-03, a delegated review of your responses and corrections was provided by member(s) of the MUHC REB. The research project was found to meet scientific and ethical standards for conduct at the MUHC.

The following documents were approved or acknowledged by the MUHC REB:

- Initial Submission Form (F11-42143)
- REB Conditions & PI Responses Form(s) (F20-60453, F20-67730)
- Drug Info Sheet (V3 2020-06-22)
- Ketotifen Safety Data Sheet (undated)
- Investigators Brochure (V2.0 2019-09-17)
- Pharmacy Manual (V1.0 2019-08-19)
- Product Monograph Zaditen (2012-08-15)
- Study Medication Request (2019-04-25)
- Research Protocol (V 5.0 2019-10-04)
- DASH Questionnaire (V3.0 2020-01-09) in English
- DASH Questionnaire (2006-01-01) in French
- OES Questionnaire (V3.0 2020-01-09) in English
- OES Questionnaire (2018-07-02] in French
- PCS Questionnaire (V3.0 2020-01-09) in English
- PCS Questionnaire (V1 1995-01-01) in French
- Participant Diary Page 1 (2018-11-28)
- Participant Diary Page 2 (2018-11-28)
- HEP Guidelines ( 2018-05-29) in French and English
- Drug Diary (V3.0 2020-10-15) in French and English
- Principal Investigator's Commitment and Signature (2020-03-06)

- Information & Consent Form (V2 2020-10-15) in French and English
- Wallet Cards (V2 2019-09-18) in French and English
- Health Canada NOL ( 2018-08-09)
- Approval of the Department / Division Head (2020-02-20)
- Case Report Forms (V2 2019-10-15)
- External Science Review ( 02/08/2017-02/10/2017)
- Drug Info Sheet (V3 2020-06-22) in French and English

This will be reported to the MUHC REB and will be entered accordingly into the minutes of the next CT2 Panel meeting. Please be advised that you may only initiate the study after all required reviews and decisions are received and documented and you have received the MUHC authorization letter.

**The approval of the research project is valid until 2022-03-03.**

All research involving human subjects requires review at recurring intervals. To comply with the regulation for continuing review of at least once per year, it is the responsibility of the investigator to submit an *Annual Renewal Submission Form (F9)* to the REB prior to expiry. Please be advised that should the protocol reach its expiry before a Continuing review has been submitted, the data collected after the expiry date may not be considered valid. However, should the research conclude for any reason prior to approval expiry, you are required to submit a *Completion (End of Study) Report (F10)* to the board once the data analysis is complete to give an account of the study findings and publication status.

Furthermore, should any revision to the project or other development occur prior to the next continuing review, you must advise the REB without delay. Regulation does not permit initiation of a proposed study modification prior to its approval by the REB.

The MUHC REB is registered and works under the published guidelines of the *Tri-Council Policy Statement 2*, in compliance with the *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (MSSS, 1998) and the *Food and Drugs Act* (2001.06.07), acting in conformity with standards set forth in the (US) *Code of Federal Regulations* governing human subjects research and functioning in a manner consistent with internationally accepted principles of good clinical practice.

We trust this will prove satisfactory to you. Thank you for your consideration in this matter.

Best Regards,



Sheldon Levy  
 MUHC REB Coordinator  
 for MUHC REB Co-chair mentioned above

**From:** [Gerardo Duque](#)  
**To:** [Payne, Kyrsten \[FH\]](#); [Spicer, Ella \[FH\]](#)  
**Subject:** FW: A-20465.m HRPO Approval Memorandum (Proposal Log Number OR160026, Award Number W81XWH-17-1-0665) (UNCLASSIFIED)  
**Date:** Friday, May 14, 2021 8:23:00 AM

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Good morning RCH team,

See below for your HRPO approval memo. Print and file for your records.

Thank you so much for your hard work in getting this through. Onwards to SIV's and getting this project home 😊

Best,

Gerry

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**From:** Mendoza, Jessica L CIV USARMY HQ USAMRDC (USA) <jessica.l.mendoza19.civ@mail.mil>  
**Sent:** Friday, May 14, 2021 8:21 AM  
**To:** 'fmoola@me.com' <fmoola@me.com>  
**Cc:** Bennett, Jodi H CIV USARMY FUTURES COMMAND (USA) <jodi.h.bennett.civ@mail.mil>; Lorna Very <very@ucalgary.ca>; Gerardo Duque <gerardo.duque@ucalgary.ca>; Kevin A. Hildebrand <hildebrk@ucalgary.ca>; Grenier, Kenneth E CIV USARMY USAMRAA (USA) <kenneth.e.grenier2.civ@mail.mil>; Roach, Akua CIV USARMY CDMRP (USA) <akua.roach.civ@mail.mil>; Odam, Kimberly L CIV USARMY HQ USAMRDC (USA) <kimberly.l.odam.civ@mail.mil>; Kline, Andrea J CIV USARMY HQ USAMRDC (USA) <andrea.j.kline.civ@mail.mil>; Mendoza, Jessica L CIV USARMY HQ USAMRDC (USA) <jessica.l.mendoza19.civ@mail.mil>; Frederick, Margaret M CTR USARMY FUTURES COMMAND (USA) <margaret.m.frederick.ctr@mail.mil>; Ofosu-Appiah, Nina Marie M CTR USARMY FUTURES COMMAND (USA) <ninamarie.m.ofosu-appiah.ctr@mail.mil>  
**Subject:** A-20465.m HRPO Approval Memorandum (Proposal Log Number OR160026, Award Number W81XWH-17-1-0665) (UNCLASSIFIED)

[**EXTERNAL**]

**CLASSIFICATION: UNCLASSIFIED**

**SUBJECT:** Initial Approval for the Protocol, “PrEvention of post-traumatic joint contractuRes with Ketotifen 2 (PERK 2),” Submitted by Farhad Moola, MD, Royal Columbian Hospital (RCH), New Westminster, British Columbia, Canada, in Support of the Proposal, “PrEvention of post-traumatic joint contractuRes with Ketotifen II (PERK II),” Submitted by Kevin A. Hildebrand, MD, University of Calgary - Health Research Innovation Centre, Calgary, Alberta, Canada, Project Identification Number 313-2019, Proposal Log Number OR160026, Award Number W81XWH-17-1-0665, HRPO Log Number A-20465.m (RCH Site)

1. The subject protocol (version 6.0 dated 15 October 2020) was approved by the Fraser Health Research Ethics Board on 26 April 2021. The U.S. Army Medical Research and Development Command (USAMRDC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) reviewed the protocol and found that it complies with applicable DoD, U.S. Army, and USAMRDC human subjects protection requirements.
2. The USAMRDC ORP HRPO approved this greater than minimal risk study for the enrollment of 702 subjects across all study sites and 50 subjects at the RCH site.
3. The Principal Investigator has a duty and responsibility to foster open and honest communication with research subjects. The USAMRDC strongly encourages the Principal Investigator to provide subjects with a copy of the research protocol, if requested, with proprietary and personal information redacted as needed.
4. The Principal Investigator must provide the following post-approval submissions to the HRPO via email to [usarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil](mailto:usarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil). Failure to comply could result in suspension or termination of funding.
  - a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRDC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution (Note: HRPO review and approval of institution is required.), change to the Institutional Review Board (IRB) of Record, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.
  - b. A copy of the IRB continuing review approval letter must be submitted to the HRPO as soon as possible after receipt of approval. According to our records, it appears the next continuing review by the IRB is due no later than 21 April 2022. Please note that the HRPO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.
  - c. The final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.
  - d. The following study events must be promptly reported to the HRPO by telephone (301-619-2165), by email ([usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil](mailto:usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil)), by facsimile (301-619-7803), or mail to the U.S. Army Medical Research and Development Command, ATTN: FCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

- (1) All unanticipated problems involving risk to subjects or others.
  - (2) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.
  - (3) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.
  - (4) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.
  - (5) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.
  - (6) Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC ORP HRPO. The report must include actions taken by the institution and the IRB.
- e. Events or protocol reports received by the HRPO that do not meet reporting requirements identified within this memorandum will be included in the HRPO study file but will not be acknowledged.

5. Please note: The USAMRDC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

6. Do not construe this correspondence as approval for any contract or grant/cooperative agreement funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds by notice of official award documentation. It is recommended that you contact the appropriate contract/grants specialist or Contracting/Grants Officer regarding the expenditure of funds for your project.

7. The HRPO point of contact for this approval is Margaret M. Frederick, PhD, Human Subjects Protection Scientist, at 301-619-7418, DSN 343-7418, or [margaret.m.frederick.ctr@mail.mil](mailto:margaret.m.frederick.ctr@mail.mil).

8. The HRPO point of contact for post-approval oversight is Nina Ofosu-Appiah, Human Subjects Protection Scientist, at 301-619-7550, DSN 343-7550, or [ninamarie.m.ofosu-appiah.ctr@mail.mil](mailto:ninamarie.m.ofosu-appiah.ctr@mail.mil).

JESSICA L. MENDOZA, BA, BSN

Human Subjects Protection Scientist and Regulatory Liaison  
Human Research Protection Office  
Office of Research Protections  
U.S. Army Medical Research and Development Command

CLASSIFICATION: UNCLASSIFIED

**From:** [Gerardo Duque](#)  
**To:** [Mary Amedeo \(CUSM\)](#)  
**Subject:** FW: A-20465.n HRPO Approval Memorandum (Proposal Log Number OR160026, Award Number W81XWH-17-1-0665) (UNCLASSIFIED)  
**Date:** Friday, August 20, 2021 1:35:34 PM

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Hi Mary,

Good news! HRPO has approved the PERK 2 to trial for McGill University Health Centre. This is the last regulatory steps in order to being all procedures for study start up. See below for correspondence from HRPO for your records.

The next step is to schedule our Site Initiation Visit, which is done virtually, with your Principal Investigator, your pharmacy team, and you. Let's discuss what times work for you and the team so we can finalize all training necessary to start the trial.

Let me know if you have any questions.

Best,

--

Gerardo "Gerry" Duque, MA  
Clinical Research Coordinator, Orthopaedic Trauma  
University of Calgary/Peter Lougheed Centre  
Phone: (403) 943 5556  
Email: [Gerardo.duque@ucalgary.ca](mailto:Gerardo.duque@ucalgary.ca)

---

**From:** Mendoza, Jessica L CIV USARMY HQ USAMRDC (USA)  
<[jessica.l.mendoza19.civ@mail.mil](mailto:jessica.l.mendoza19.civ@mail.mil)>  
**Date:** Friday, August 20, 2021 at 1:22 PM  
**To:** [edward.harvey@mcgill.ca](mailto:edward.harvey@mcgill.ca) <[edward.harvey@mcgill.ca](mailto:edward.harvey@mcgill.ca)>  
**Cc:** Bennett, Jodi H CIV USARMY FUTURES COMMAND (USA) <[jodi.h.bennett.civ@mail.mil](mailto:jodi.h.bennett.civ@mail.mil)>, Gerardo Duque <[gerardo.duque@ucalgary.ca](mailto:gerardo.duque@ucalgary.ca)>, Kevin A. Hildebrand <[hildebrk@ucalgary.ca](mailto:hildebrk@ucalgary.ca)>, Odam, Kimberly L CIV USARMY HQ USAMRDC (USA) <[kimberly.l.odam.civ@mail.mil](mailto:kimberly.l.odam.civ@mail.mil)>, Kline, Andrea J CIV USARMY HQ USAMRDC (USA) <[andrea.j.kline.civ@mail.mil](mailto:andrea.j.kline.civ@mail.mil)>, Ofosu-Appiah, Nina Marie M CTR USARMY FUTURES COMMAND (USA) <[ninamarie.m.ofosu-appiah.ctr@mail.mil](mailto:ninamarie.m.ofosu-appiah.ctr@mail.mil)>, Mendoza, Jessica L CIV USARMY HQ USAMRDC (USA) <[jessica.l.mendoza19.civ@mail.mil](mailto:jessica.l.mendoza19.civ@mail.mil)>, Frederick, Margaret M CTR USARMY FUTURES COMMAND (USA) <[margaret.m.frederick.ctr@mail.mil](mailto:margaret.m.frederick.ctr@mail.mil)>, Yadav, Prem CIV USARMY CDMRP (USA) <[prem.yadav.civ@mail.mil](mailto:prem.yadav.civ@mail.mil)>, [mary.amedeo@muhc.mcgill.ca](mailto:mary.amedeo@muhc.mcgill.ca) <[mary.amedeo@muhc.mcgill.ca](mailto:mary.amedeo@muhc.mcgill.ca)>, Tiago Lier <[tlier@ucalgary.ca](mailto:tlier@ucalgary.ca)>, Grenier, Kenneth E CIV USARMY USAMRAA (USA) <[kenneth.e.grenier2.civ@mail.mil](mailto:kenneth.e.grenier2.civ@mail.mil)>  
**Subject:** A-20465.n HRPO Approval Memorandum (Proposal Log Number OR160026, Award Number W81XWH-17-1-0665) (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

SUBJECT: Initial Approval for the Protocol, “PrEvention of post-traumatic joint contractuRes with Ketotifen 2 (PERK 2),” Submitted by Edward J. Harvey, MD, McGill University Health Centre (MUHC), Montreal General Hospital, Montreal, Canada, in Support of the Proposal, “PrEvention of post-traumatic joint contractuRes with Ketotifen II (PERK II,” Submitted by Kevin A. Hildebrand, MD, University of Calgary - Health Research Innovation Centre, Calgary, Alberta, Canada, Proposal Log Number OR160026, Award Number W81XWH-17-1-0665, HRPO Log Number A-20465.n (MUCH Site)

1. The subject protocol (version 6.0 dated 15 October 2020) was approved by the MUHC Research Ethics Board on 30 July 2021. The U.S. Army Medical Research and Development Command (USAMRDC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) reviewed the protocol and found that it complies with applicable DoD, U.S. Army, and USAMRDC human subjects protection requirements.
2. The USAMRDC ORP HRPO approved this greater than minimal risk study for the enrollment of 702 subjects across all study sites.
3. The Principal Investigator has a duty and responsibility to foster open and honest communication with research subjects. The USAMRDC strongly encourages the Principal Investigator to provide subjects with a copy of the research protocol, if requested, with proprietary and personal information redacted as needed.
4. The Principal Investigator must provide the following post-approval submissions to the HRPO via email to [usarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil](mailto:usarmy.detrick.medcom-usamrmc.other.hrpo-cr-documents@mail.mil). Failure to comply could result in suspension or termination of funding.
  - a. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRDC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution (Note: HRPO review and approval of institution is required.), change to the Institutional Review Board (IRB) of Record, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e. would prompt additional scientific review), or a change that could potentially increase risks to subjects.
  - b. A copy of the IRB continuing review approval letter must be submitted to the

HRPO as soon as possible after receipt of approval. According to our records, it appears the next continuing review by the IRB is due no later than 3 March 2022. Please note that the HRPO conducts random audits at the time of continuing review and additional information and documentation may be requested at that time.

c. The final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the HRPO as soon as all documents become available.

d. The following study events must be promptly reported to the HRPO by telephone (301-619-2165), by email ([usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil](mailto:usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil)), by facsimile (301-619-7803), or mail to the U.S. Army Medical Research and Development Command, ATTN: FCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

(1) All unanticipated problems involving risk to subjects or others.

(2) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

(3) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

(4) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.

(5) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

(6) Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC ORP HRPO. The report must include actions taken by the institution and the IRB.

e. Events or protocol reports received by the HRPO that do not meet reporting requirements identified within this memorandum will be included in the HRPO study file but will not be acknowledged.

5. Please note: The USAMRDC ORP HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

6. Do not construe this correspondence as approval for any contract or grant/cooperative agreement funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds by notice of official award documentation. It is

recommended that you contact the appropriate contract/grants specialist or Contracting/Grants Officer regarding the expenditure of funds for your project.

7. The HRPO point of contact for this approval is Margaret M. Frederick, PhD, Human Subjects Protection Scientist, at 301-619-7418, DSN 343-7418, or [margaret.m.frederick.ctr@mail.mil](mailto:margaret.m.frederick.ctr@mail.mil).

8. The HRPO point of contact for post-approval oversight is Nina Ofosu-Appiah, Human Subjects Protection Scientist, at 301-619-7550, DSN 343-7550, or [ninamarie.m.ofosu-appiah.ctr@mail.mil](mailto:ninamarie.m.ofosu-appiah.ctr@mail.mil).

JESSICA L. MENDOZA, BA, BSN  
Human Subjects Protection Scientist and Regulatory Liaison  
Human Research Protection Office  
Office of Research Protections  
U.S. Army Medical Research and Development Command

CLASSIFICATION: UNCLASSIFIED

**A Study Details:**

Protocol #:	PERK2_KAH	Date:	1512002020
Order # (if applicable):	1	Sponsor:	Dr. Kevin A. Hildebrand

**B Receiver Details:**

Name of Site (Centre Code):	Carolinas Medical Center
Requesting Individual:	Ryan Bender, Pharm.D.
Department / Attention:	Investigational Drug Services – Ryan Bender
Address Line 1:	1021 Morehead Medical Drive, Suite 40310
Address Line 2:	Charlotte, NC
Address Line 3:	USA
Postal Code:	28204
Telephone:	+1 980 442 4900
Email:	cmcpidrugsvc@atriumhealth.org

**C Items Requisitioned:**

Material Name	Strength	Quantity and unit of measure
Example: Product ABC	10mg	75 x 100ml
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit

List Specific Treatment Numbers (an additional list may be attached to this document):

Treatment # List	Treatment # List	Treatment # List	Treatment # List	Treatment # List	Treatment # List

**D Date Required:**

Date Required:	Click or tap to enter a date.
Temperature Range:	Requesting Individual.

EMAIL COMPLETED FORM TO [barl@barl.ca](mailto:barl@barl.ca)

Cold Chain Orders Ship Day: MONDAY, TUESDAY, or WEDNESDAY by 15:00 EST.

Ambient Temperature Orders Ship Days: MONDAY, TUESDAY, WEDNESDAY or THURSDAY by 15:00 EST.

If Order not received within 2 business days from date of order, contact:

**A Study Details:**

Protocol #:	PERK2_KAH	Date:	1512002020
Order # (if applicable):	1	Sponsor:	Dr. Kevin A. Hildebrand

**B Receiver Details:**

Name of Site (Centre Code):	Nova Scotia Health Authority/Queen Elizabeth II Health Science Centre
Requesting Individual:	Joanna Arsenault, CCRP
Department / Attention:	Halifax Infirmary/Pharmacy Department – Atte. Joanna Arsenault
Address Line 1:	Room 2417, 1796 Summer Street
Address Line 2:	Halifax, Nova Scotia
Address Line 3:	Canada
Postal Code:	B3H 3A7
Telephone:	(902) 473 2787
Email:	Joanna.arsenault@nshealth.ca

**C Items Requisitioned:**

Material Name	Strength	Quantity and unit of measure
Example: Product ABC	10mg	75 x 100ml
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit

List Specific Treatment Numbers (an additional list may be attached to this document):

Treatment # List	Treatment # List	Treatment # List	Treatment # List	Treatment # List	Treatment # List

**D Date Required:**

Date Required:	<a href="#">Click or tap to enter a date.</a>
Temperature Range:	<a href="#">Requesting Individual.</a>

**EMAIL COMPLETED FORM TO [barl@barl.ca](mailto:barl@barl.ca)**

Cold Chain Orders Ship Day: MONDAY, TUESDAY, or WEDNESDAY by 15:00 EST.

Ambient Temperature Orders Ship Days: MONDAY, TUESDAY, WEDNESDAY or THURSDAY by 15:00 EST.

**A Study Details:**

Protocol #:	PERK2_KAH	Date:	20210521
Order # (if applicable):	1	Sponsor:	Dr. Kevin Hildebrand

**B Receiver Details:**

Name of Site (Centre Code):	Royal Columbian Hospital
Requesting Individual:	Maria Chan, BSc (Pharm), ACPR
Department / Attention:	Clinical Trials Pharmacist (Pharmacy Department)
Address Line 1:	330 E Columbian Hospital
Address Line 2:	New Westminster, BC
Address Line 3:	Canada
Postal Code:	V3L 3W7
Telephone:	N/A
Email:	Maria.Chan@fraserhealth.ca

**C Items Requisitioned:**

Material Name	Strength	Quantity and unit of measure
Example: Product ABC	10mg	75 x 100ml
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit

List Specific Treatment Numbers (an additional list may be attached to this document):

Treatment # List	Treatment # List	Treatment # List	Treatment # List	Treatment # List	Treatment # List

**D Date Required:**

Date Required:	Click or tap to enter a date.
Temperature Range:	Requesting Individual.

EMAIL COMPLETED FORM TO [barl@barl.ca](mailto:barl@barl.ca)

Cold Chain Orders Ship Day: MONDAY, TUESDAY, or WEDNESDAY by 15:00 EST.

Ambient Temperature Orders Ship Days: MONDAY, TUESDAY, WEDNESDAY or THURSDAY by 15:00 EST.

If Order not received within 2 business days from date of order, contact:

**A Study Details:**

Protocol #:	PERK2_KAH	Date:	1512002020
Order # (if applicable):	1	Sponsor:	Dr. Kevin Hildebrand

**B Receiver Details:**

Name of Site (Centre Code):	Sunnybrook Health Sciences Centre
Requesting Individual:	Katrina Hatzifilalithis/Nathan Ma
Department / Attention:	Pharmacy Stores
Address Line 1:	Room KB-312, 2075 Bayview Ave,
Address Line 2:	Toronto, ON
Address Line 3:	Canada
Postal Code:	M4N 3M5
Telephone:	(416) 480 6100 ext. 5292
Email:	Katrina.fila@sunnybrook.ca

**C Items Requisitioned:**

Material Name	Strength	Quantity and unit of measure
Example: Product ABC	10mg	75 x 100ml
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit
Material Name	strength.	Quantity and unit

List Specific Treatment Numbers (an additional list may be attached to this document):

Treatment # List	Treatment # List	Treatment # List	Treatment # List	Treatment # List	Treatment # List

**D Date Required:**

Date Required:	Click or tap to enter a date.
Temperature Range:	Requesting Individual.

EMAIL COMPLETED FORM TO [barl@barl.ca](mailto:barl@barl.ca)

Cold Chain Orders Ship Day: MONDAY, TUESDAY, or WEDNESDAY by 15:00 EST.

Ambient Temperature Orders Ship Days: MONDAY, TUESDAY, WEDNESDAY or THURSDAY by 15:00 EST.

If Order not received within 2 business days from date of order, contact:

May 28, 2021

Dr. Farhad Moola MD, FRCSC  
Royal Columbian Hospital  
403-233 Nelson's Crescent  
New Westminster, BC  
V3L 0E4

**Subject: Site Initiation Visit Follow-Up for PERK 2 Trial**

Dear Dr Moola:

This letter is in follow-up to our recent Site Initiation Visits performed on May 17 and May 27, 2021. The initiation visit included review of the following:

- Study Personnel and Facilities
- Study Protocol
- Pharmacy
- Subject Recruitment Procedures
- Informed Consent Procedures
- Urine Pregnancy Testing Procedures
- Participant Screening & Enrollment Logs
- Case Report Forms
- Electronic Data Capture System (REDCap)
- Drug Tracking System (IWRS)
- (Serious) Adverse Event Reporting

We are pleased to announce that your site can **begin enrollment** as of receipt and availability of drug at your site. Your site is set to receive PERK 2 Investigational Product by June 16, 2021.

I would like to thank you on behalf of our PERK 2 Team for your participation in this clinic trial and I look forward to working with you and your study team. Please feel free to contact me at 403-819-4985 or by email at [hildebrk@ucalgary.ca](mailto:hildebrk@ucalgary.ca) if you have any additional questions or concerns.

Thank you for your continued support of the **PERK 2 Trial!**

Sincerely,



Dr. Kevin A. Hildebrand, MD, FRCSC, CCPE  
PERK 2 Sponsor and Primary Investigator, Peter Lougheed Centre  
Professor, Department of Surgery  
University of Calgary and Alberta Health Services – Calgary Zone

14 December 2020

Dr. Andrew Trenholm, Qualified Investigator  
Queen Elizabeth II Health Sciences Centre (Site #7)  
1276 South Park Street,  
Halifax, Nova Scotia, Canada

**Subject: Site Initiation Visit Follow-Up for PERK 2 Trial**

Dear Dr. Trenholm,

This letter is in follow-up to my recent Site Initiation Visit performed on December 1<sup>st</sup>, 7<sup>th</sup>, and 10<sup>th</sup>. The initiation visit included review of the following:

- Study Personnel and Facilities
- Study Protocol
- Pharmacy
- Subject Recruitment Procedures
- Informed Consent Procedures
- Urine Pregnancy Testing Procedures
- Participant Screening & Enrollment Logs
- Case Report Forms
- Electronic Data Capture System (REDCap)
- Drug Tracking System (IWRS)
- (Serious) Adverse Event Reporting

The following are responses to questions raised during the visit:

Question	Response
Is the re-ordering drug process automatically generated?	Email reminders will be sent to the Sponsor when drug is expiring in 90 days, 6 weeks, and if 1 of the 3 arms of drug is low. Coordinating Centre will engage with the site about re-ordering.
Can sites create their own medication request forms?	Yes, this is fine. Please use our current template to modify and send completed copy to the Coordinating Centre for approval.
Is surgical sterilization (tubal ligation and hysterectomy) and vasectomy sufficient as the primary form of contraception?	Yes, so long as you can find written documentation/history about this in their patient chart.

Are baseline questionnaires for pre-injury status or injury status?	Baseline questionnaires are reported as pre-injury status.
Do we require documentation of consent if we are using a similar document for all patients?	No, you can use your site-specific document for this. Please send this document to the coordinating centre so we have it on file.

We are pleased to announce that your site is now **approved to enroll** following the receipt of the trial medication expected to arrive on Jan 15, 2021. This process may be delayed due to possible disruptions of distribution from COVID-19.

We will be in touch for any future drug requirements, SAE reporting, and any questions or concerns about the PERK 2 Trial.

We would like to schedule the first monitor session with Jackie Busheikin after 3-5 participants are successfully randomized into the PERK 2 Trial.

I would like to thank you on behalf of our PERK 2 Team for your participation in this clinic trial and I look forward to working with you and your study team. Please feel free to contact me at 403-819-4985 or by email at [hildebrk@ucalgary.ca](mailto:hildebrk@ucalgary.ca) if you have any additional questions or concerns.

Thank you for your continued support of the **PERK 2 Trial!**

Sincerely,



Dr. Kevin A. Hildebrand, MD, FRCSC, CCPE  
 PERK 2 Sponsor and Primary Investigator, Peter Lougheed Centre  
 Professor, Department of Surgery  
 University of Calgary and Alberta Health Services – Calgary Zone

## Data Exports, Reports, and Stats

### Randomized Subjects

 Table not displaying properly [?](#)

Screening ID screen_id	Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	Data Access Group redcap_data_access_group	BOTTLE ID rand_group	Date of randomization rand_dt
<a href="#">5358-4</a> (Participant ID 01-001)	Screening/Randomization			Peter Lougheed Centre	10008	2019-06-29
<a href="#">5362-2</a> (Participant ID 05-001)	Screening/Randomization			South Health Campus	10072	2019-07-02
<a href="#">5362-13</a> (Participant ID 05-002)	Screening/Randomization			South Health Campus	10049	2019-07-26
<a href="#">5358-5</a> (Participant ID 01-002)	Screening/Randomization			Peter Lougheed Centre	10001	2019-07-27
<a href="#">5358-47</a> (Participant ID 01-003)	Screening/Randomization			Peter Lougheed Centre	10006	2019-08-29
<a href="#">5362-31</a> (Participant ID 05-003)	Screening/Randomization			South Health Campus	10073	2019-09-03
<a href="#">5362-34</a> (Participant ID 05-004)	Screening/Randomization			South Health Campus	10066	2019-09-04
<a href="#">5358-56</a> (Participant ID 01-004)	Screening/Randomization			Peter Lougheed Centre	10020	2019-09-11
<a href="#">5362-39</a> (Participant ID 05-005)	Screening/Randomization			South Health Campus	10050	2019-09-17
<a href="#">5358-70</a> (Participant ID 01-005)	Screening/Randomization			Peter Lougheed Centre	10012	2019-10-11
<a href="#">5362-46</a> (Participant ID 05-006)	Screening/Randomization			South Health Campus	10068	2019-10-15
<a href="#">5370-1</a> (Participant ID 13-001)	Screening/Randomization			Sturgeon Community Hospital	10113	2019-10-16
<a href="#">5370-3</a> (Participant ID 13-002)	Screening/Randomization			Sturgeon Community Hospital	10107	2019-10-28
<a href="#">5370-4</a> (Participant ID 13-003)	Screening/Randomization			Sturgeon Community Hospital	10101	2019-10-29
<a href="#">5362-56</a> (Participant ID 05-007)	Screening/Randomization			South Health Campus	10053	2019-11-05
<a href="#">5358-77</a> (Participant ID 01-006)	Screening/Randomization			Peter Lougheed Centre	10009	2019-11-08
<a href="#">5370-6</a> (Participant ID 13-004)	Screening/Randomization			Sturgeon Community Hospital	10102	2019-11-20
<a href="#">5358-87</a> (Participant ID 01-007)	Screening/Randomization			Peter Lougheed Centre	10011	2019-11-29
<a href="#">5370-8</a> (Participant ID 13-005)	Screening/Randomization			Sturgeon Community Hospital	10108	2019-12-04
<a href="#">5360-1</a> (Participant ID 03-001)	Screening/Randomization			Foothills Medical Centre	10037	2019-12-06
<a href="#">5360-3</a> (Participant ID 03-002)	Screening/Randomization			Foothills Medical Centre	10036	2019-12-09
<a href="#">5362-71</a> (Participant ID 05-008)	Screening/Randomization			South Health Campus	10070	2019-12-10
<a href="#">5362-72</a> (Participant ID 05-009)	Screening/Randomization			South Health Campus	10079	2019-12-10
<a href="#">5358-93</a> (Participant ID 01-008)	Screening/Randomization			Peter Lougheed Centre	10030	2019-12-20
<a href="#">5360-5</a> (Participant ID 03-003)	Screening/Randomization			Foothills Medical Centre	10028	2019-12-23
<a href="#">5362-81</a> (Participant ID 05-010)	Screening/Randomization			South Health Campus	10056	2019-12-26
<a href="#">5368-1</a> (Participant ID 11-001)	Screening/Randomization			The Ottawa Hospital, Civic Campus	10155	2020-01-10
<a href="#">5358-103</a> (Participant ID 01-009)	Screening/Randomization			Peter Lougheed Centre	10203	2020-01-23
<a href="#">5358-104</a> (Participant ID 01-010)	Screening/Randomization			Peter Lougheed Centre	10197	2020-01-24
<a href="#">5362-92</a> (Participant ID 05-011)	Screening/Randomization			South Health Campus	10233	2020-01-27
<a href="#">5362-94</a> (Participant ID 05-012)	Screening/Randomization			South Health Campus	10239	2020-02-04

Screening ID screen_id	Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	Data Access Group redcap_data_access_group	BOTTLE ID rand_group	Date of randomization rand_dt
<a href="#">5360-10</a> (Participant ID 03-004)	Screening/Randomization			Foothills Medical Centre	10219	2020-02-05
<a href="#">5359-10</a> (Participant ID 02-001)	Screening/Randomization			University of Maryland Medical Center	10131	2020-02-07
<a href="#">5369-1</a> (Participant ID 12-001)	Screening/Randomization			The Ottawa Hospital, General Campus	10185	2020-02-11
<a href="#">5360-12</a> (Participant ID 03-005)	Screening/Randomization			Foothills Medical Centre	10209	2020-02-12
<a href="#">5370-11</a> (Participant ID 13-006)	Screening/Randomization			Sturgeon Community Hospital	10103	2020-02-17
<a href="#">5370-12</a> (Participant ID 13-007)	Screening/Randomization			Sturgeon Community Hospital	10114	2020-02-21
<a href="#">5374-1</a> (Participant ID 17-001)	Screening/Randomization			University of Vermont Medical Center	10245	2020-02-27
<a href="#">5358-120</a> (Participant ID 01-011)	Screening/Randomization			Peter Lougheed Centre	10204	2020-03-02
<a href="#">5362-104</a> (Participant ID 05-013)	Screening/Randomization			South Health Campus	10227	2020-03-02
<a href="#">5359-14</a> (Participant ID 02-002)	Screening/Randomization			University of Maryland Medical Center	10125	2020-03-03
<a href="#">5358-122</a> (Participant ID 01-012)	Screening/Randomization			Peter Lougheed Centre	10198	2020-03-05
<a href="#">5358-125</a> (Participant ID 01-013)	Screening/Randomization			Peter Lougheed Centre	10191	2020-03-12
<a href="#">5374-2</a> (Participant ID 17-002)	Screening/Randomization			University of Vermont Medical Center	10251	2020-03-16
<a href="#">5358-126</a> (Participant ID 01-014)	Screening/Randomization			Peter Lougheed Centre	10192	2020-06-30
<a href="#">5362-108</a> (Participant ID 05-014)	Screening/Randomization			South Health Campus	10234	2020-07-17
<a href="#">5374-3</a> (Participant ID 17-003)	Screening/Randomization			University of Vermont Medical Center	10257	2020-07-27
<a href="#">5368-16</a> (Participant ID 11-002)	Screening/Randomization			The Ottawa Hospital, Civic Campus	10166	2020-08-20
<a href="#">5369-10</a> (Participant ID 12-002)	Screening/Randomization			The Ottawa Hospital, General Campus	10186	2020-09-22
<a href="#">5369-11</a> (Participant ID 12-003)	Screening/Randomization			The Ottawa Hospital, General Campus	10173	2020-10-01
<a href="#">5358-141</a> (Participant ID 01-015)	Screening/Randomization			Peter Lougheed Centre	10193	2020-10-02
<a href="#">5358-142</a> (Participant ID 01-016)	Screening/Randomization			Peter Lougheed Centre	10199	2020-10-14
<a href="#">5358-143</a> (Participant ID 01-017)	Screening/Randomization			Peter Lougheed Centre	10205	2020-10-22
<a href="#">5362-118</a> (Participant ID 05-015)	Screening/Randomization			South Health Campus	10235	2020-10-24
<a href="#">5358-144</a> (Participant ID 01-018)	Screening/Randomization			Peter Lougheed Centre	10206	2020-10-27
<a href="#">5359-16</a> (Participant ID 02-003)	Screening/Randomization			University of Maryland Medical Center	10119	2020-10-31
<a href="#">5371-20</a> (Participant ID 14-001)	Screening/Randomization			St. Michael's Hospital	10143	2020-11-10
<a href="#">5371-21</a> (Participant ID 14-002)	Screening/Randomization			St. Michael's Hospital	10149	2020-11-10
<a href="#">5373-4</a> (Participant ID 16-001)	Screening/Randomization			St. Paul's Hospital	20263	2020-11-18
<a href="#">5370-13</a> (Participant ID 13-008)	Screening/Randomization			Sturgeon Community Hospital	20326	2020-11-20
<a href="#">5358-154</a> (Participant ID 01-019)	Screening/Randomization			Peter Lougheed Centre	10200	2020-11-23
<a href="#">5369-16</a> (Participant ID 12-004)	Screening/Randomization			The Ottawa Hospital, General Campus	20317	2020-12-01
<a href="#">5362-131</a> (Participant ID 05-016)	Screening/Randomization			South Health Campus	10228	2020-12-15
<a href="#">5358-164</a> (Participant ID 01-020)	Screening/Randomization			Peter Lougheed Centre	10194	2020-12-29

<b>Screening ID</b> screen_id	<b>Event Name</b> redcap_event_name	<b>Repeat Instrument</b> redcap_repeat_instrument	<b>Repeat Instance</b> redcap_repeat_instance	<b>Data Access Group</b> redcap_data_access_group	<b>BOTTLE ID</b> rand_group	<b>Date of randomization</b> rand_dt
<a href="#">5373-6</a> (Participant ID 16-002)	Screening/Randomization			St. Paul's Hospital	20275	2021-01-13
<a href="#">5362-136</a> (Participant ID 05-017)	Screening/Randomization			South Health Campus	10240	2021-01-18
<a href="#">5358-167</a> (Participant ID 01-021)	Screening/Randomization			Peter Lougheed Centre	10195	2021-01-19
<a href="#">5362-137</a> (Participant ID 05-018)	Screening/Randomization			South Health Campus	10229	2021-01-19
<a href="#">5373-7</a> (Participant ID 16-003)	Screening/Randomization			St. Paul's Hospital	20269	2021-01-19
<a href="#">5358-168</a> (Participant ID 01-022)	Screening/Randomization			Peter Lougheed Centre	10196	2021-01-20
<a href="#">5370-14</a> (Participant ID 13-009)	Screening/Randomization			Sturgeon Community Hospital	20327	2021-01-20
<a href="#">5369-26</a> (Participant ID 12-005)	Screening/Randomization			The Ottawa Hospital, General Campus	20318	2021-01-22
<a href="#">5360-29</a> (Participant ID 03-006)	Screening/Randomization			Foothills Medical Centre	10220	2021-02-08
<a href="#">5360-30</a> (Participant ID 03-007)	Screening/Randomization			Foothills Medical Centre	10214	2021-02-08
<a href="#">5364-1</a> (Participant ID 07-001)	Screening/Randomization			Queen Elizabeth II Health Sciences Centre	20351	2021-02-09
<a href="#">5372-1</a> (Participant ID 15-001)	Screening/Randomization			Sunnybrook Health Sciences Centre	20358	2021-02-11
<a href="#">5369-28</a> (Participant ID 12-006)	Screening/Randomization			The Ottawa Hospital, General Campus	20319	2021-02-12
<a href="#">5370-16</a> (Participant ID 13-010)	Screening/Randomization			Sturgeon Community Hospital	20328	2021-03-03
<a href="#">5372-2</a> (Participant ID 15-002)	Screening/Randomization			Sunnybrook Health Sciences Centre	20359	2021-03-04
<a href="#">5359-36</a> (Participant ID 02-004)	Screening/Randomization			University of Maryland Medical Center	20299	2021-03-05
<a href="#">5360-34</a> (Participant ID 03-008)	Screening/Randomization			Foothills Medical Centre	10215	2021-03-08
<a href="#">5360-35</a> (Participant ID 03-009)	Screening/Randomization			Foothills Medical Centre	10210	2021-03-09
<a href="#">5364-5</a> (Participant ID 07-002)	Screening/Randomization			Queen Elizabeth II Health Sciences Centre	20352	2021-03-11
<a href="#">5362-138</a> (Participant ID 05-019)	Screening/Randomization			South Health Campus	10241	2021-03-12
<a href="#">5358-171</a> (Participant ID 01-023)	Screening/Randomization			Peter Lougheed Centre	10201	2021-03-14
<a href="#">5374-11</a> (Participant ID 17-004)	Screening/Randomization			University of Vermont Medical Center	10258	2021-03-18
<a href="#">5362-141</a> (Participant ID 05-020)	Screening/Randomization			South Health Campus	10242	2021-03-24
<a href="#">5359-52</a> (Participant ID 02-005)	Screening/Randomization			University of Maryland Medical Center	20300	2021-03-26
<a href="#">5362-143</a> (Participant ID 05-021)	Screening/Randomization			South Health Campus	10236	2021-03-31
<a href="#">5370-18</a> (Participant ID 13-011)	Screening/Randomization			Sturgeon Community Hospital	20329	2021-04-03
<a href="#">5358-174</a> (Participant ID 01-024)	Screening/Randomization			Peter Lougheed Centre	10202	2021-04-07
<a href="#">5359-53</a> (Participant ID 02-006)	Screening/Randomization			University of Maryland Medical Center	20301	2021-04-08
<a href="#">5370-21</a> (Participant ID 13-012)	Screening/Randomization			Sturgeon Community Hospital	20330	2021-04-09
<a href="#">5360-36</a> (Participant ID 03-010)	Screening/Randomization			Foothills Medical Centre	20374	2021-04-19
<a href="#">5374-13</a> (Participant ID 17-005)	Screening/Randomization			University of Vermont Medical Center	20392	2021-04-24
<a href="#">5358-175</a> (Participant ID 01-025)	Screening/Randomization			Peter Lougheed Centre	20365	2021-05-04
<a href="#">5362-144</a> (Participant ID 05-022)	Screening/Randomization			South Health Campus	20383	2021-05-06

<b>Screening ID</b> screen_id	<b>Event Name</b> redcap_event_name	<b>Repeat Instrument</b> redcap_repeat_instrument	<b>Repeat Instance</b> redcap_repeat_instance	<b>Data Access Group</b> redcap_data_access_group	<b>BOTTLE ID</b> rand_group	<b>Date of randomization</b> rand_dt
<a href="#">5370-22</a> (Participant ID 13-013)	Screening/Randomization			Sturgeon Community Hospital	20331	2021-05-06
<a href="#">5358-177</a> (Participant ID 01-026)	Screening/Randomization			Peter Lougheed Centre	20366	2021-05-07
<a href="#">5372-3</a> (Participant ID 15-003)	Screening/Randomization			Peter Lougheed Centre	20360	2021-05-07
<a href="#">5359-54</a> (Participant ID 02-007)	Screening/Randomization			University of Maryland Medical Center	20302	2021-05-10
<a href="#">5359-55</a> (Participant ID 02-008)	Screening/Randomization			University of Maryland Medical Center	20303	2021-05-11
<a href="#">5360-37</a> (Participant ID 03-011)	Screening/Randomization			Foothills Medical Centre	20375	2021-05-17
<a href="#">5359-56</a> (Participant ID 02-009)	Screening/Randomization			University of Maryland Medical Center	20304	2021-05-18
<a href="#">5358-179</a> (Participant ID 01-027)	Screening/Randomization			Peter Lougheed Centre	20367	2021-05-20
<a href="#">5363-5</a> (Participant ID 06-001)	Screening/Randomization			Carolinas Medical Center	20344	2021-05-21
<a href="#">5369-48</a> (Participant ID 12-007)	Screening/Randomization			The Ottawa Hospital, General Campus	20320	2021-05-25
<a href="#">5362-147</a> (Participant ID 05-023)	Screening/Randomization			South Health Campus	20384	2021-05-28
<a href="#">5373-8</a> (Participant ID 16-004)	Screening/Randomization			St. Paul's Hospital	20270	2021-06-02
<a href="#">5360-39</a> (Participant ID 03-012)	Screening/Randomization			Sturgeon Community Hospital	20376	2021-06-03
<a href="#">5374-18</a> (Participant ID 17-006)	Screening/Randomization			University of Vermont Medical Center	20393	2021-06-05
<a href="#">5374-19</a> (Participant ID 17-007)	Screening/Randomization			University of Vermont Medical Center	20394	2021-06-10
<a href="#">5374-20</a> (Participant ID 17-008)	Screening/Randomization			University of Vermont Medical Center	20395	2021-06-11
<a href="#">5362-149</a> (Participant ID 05-024)	Screening/Randomization			South Health Campus	20385	2021-06-14
<a href="#">5360-41</a> (Participant ID 03-013)	Screening/Randomization			Foothills Medical Centre	20377	2021-06-15
<a href="#">5360-44</a> (Participant ID 03-014)	Screening/Randomization			Foothills Medical Centre	20378	2021-06-18
<a href="#">5362-151</a> (Participant ID 05-025)	Screening/Randomization			South Health Campus	20386	2021-06-18
<a href="#">5370-23</a> (Participant ID 13-014)	Screening/Randomization			Sturgeon Community Hospital	20332	2021-06-18
<a href="#">5362-152</a> (Participant ID 05-026)	Screening/Randomization			South Health Campus	20387	2021-06-23
<a href="#">5358-180</a> (Participant ID 01-028)	Screening/Randomization			Peter Lougheed Centre	20368	2021-06-24
<a href="#">5360-47</a> (Participant ID 03-015)	Screening/Randomization			Foothills Medical Centre	20379	2021-06-24
<a href="#">5374-22</a> (Participant ID 17-009)	Screening/Randomization			University of Vermont Medical Center	20396	2021-06-25
<a href="#">5374-23</a> (Participant ID 17-010)	Screening/Randomization			University of Vermont Medical Center	20397	2021-06-28
<a href="#">5362-153</a> (Participant ID 05-027)	Screening/Randomization			South Health Campus	20388	2021-06-29
<a href="#">5370-24</a> (Participant ID 13-015)	Screening/Randomization			Sturgeon Community Hospital	20431	2021-07-02
<a href="#">5362-154</a> (Participant ID 05-028)	Screening/Randomization			South Health Campus	20389	2021-07-05
<a href="#">5360-49</a> (Participant ID 03-016)	Screening/Randomization			Foothills Medical Centre	20380	2021-07-06
<a href="#">5371-23</a> (Participant ID 14-003)	Screening/Randomization			St. Michael's Hospital	20437	2021-07-12
<a href="#">5367-2</a> (Participant ID 10-001)	Screening/Randomization			Royal Columbian Hospital	20416	2021-07-13
<a href="#">5362-158</a> (Participant ID 05-029)	Screening/Randomization			South Health Campus	20390	2021-07-15

Screening ID screen_id	Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	Data Access Group redcap_data_access_group	BOTTLE ID rand_group	Date of randomization rand_dt
<a href="#">5362-160</a> (Participant ID 05-030)	Screening/Randomization			South Health Campus	20391	2021-07-16
<a href="#">5365-1</a> (Participant ID 08-001)	Screening/Randomization			St. Joseph's Hospital	20413	2021-07-16
<a href="#">5367-3</a> (Participant ID 10-002)	Screening/Randomization			Royal Columbian Hospital	20417	2021-07-16
<a href="#">5360-56</a> (Participant ID 03-017)	Screening/Randomization			Sturgeon Community Hospital	20381	2021-07-20
<a href="#">5359-57</a> (Participant ID 02-010)	Screening/Randomization			University of Maryland Medical Center	20398	2021-07-27
<a href="#">5369-63</a> (Participant ID 12-008)	Screening/Randomization			The Ottawa Hospital, General Campus	20425	2021-07-27
<a href="#">5364-10</a> (Participant ID 07-003)	Screening/Randomization			Queen Elizabeth II Health Sciences Centre	20407	2021-07-28
<a href="#">5362-164</a> (Participant ID 05-031)	Screening/Randomization			South Health Campus	20473	2021-08-04
<a href="#">5367-4</a> (Participant ID 10-003)	Screening/Randomization			Royal Columbian Hospital	20418	2021-08-06
<a href="#">5367-7</a> (Participant ID 10-004)	Screening/Randomization			Royal Columbian Hospital	20419	2021-08-12
<a href="#">5358-184</a> (Participant ID 01-029)	Screening/Randomization			Peter Lougheed Centre	20369	2021-08-14
<a href="#">5365-2</a> (Participant ID 08-002)	Screening/Randomization			St. Joseph's Hospital	20414	2021-08-17
<a href="#">5367-9</a> (Participant ID 10-005)	Screening/Randomization			Royal Columbian Hospital	20420	2021-08-19
<a href="#">5371-24</a> (Participant ID 14-004)	Screening/Randomization			St. Michael's Hospital	20438	2021-08-19
<a href="#">5358-186</a> (Participant ID 01-030)	Screening/Randomization			Peter Lougheed Centre	20370	2021-08-25
<a href="#">5374-25</a> (Participant ID 17-011)	Screening/Randomization			University of Vermont Medical Center	20485	2021-08-25
<a href="#">5360-60</a> (Participant ID 03-018)	Screening/Randomization			Foothills Medical Centre	20382	2021-08-27
<a href="#">5362-168</a> (Participant ID 05-032)	Screening/Randomization			South Health Campus	20479	2021-08-30
<a href="#">5359-81</a> (Participant ID 02-011)	Screening/Randomization			University of Maryland Medical Center	20399	2021-08-31
<a href="#">5362-169</a> (Participant ID 05-033)	Screening/Randomization			South Health Campus	20476	2021-09-02
<a href="#">5360-61</a> (Participant ID 03-019)	Screening/Randomization			Foothills Medical Centre	20467	2021-09-03
<a href="#">5360-62</a> (Participant ID 03-020)	Screening/Randomization			Foothills Medical Centre	20464	2021-09-03
<a href="#">5362-170</a> (Participant ID 05-034)	Screening/Randomization			South Health Campus	20477	2021-09-06
<a href="#">5360-63</a> (Participant ID 03-021)	Screening/Randomization			Foothills Medical Centre	20470	2021-09-08
<a href="#">5374-27</a> (Participant ID 17-012)	Screening/Randomization			University of Vermont Medical Center	20488	2021-09-09
<a href="#">5360-64</a> (Participant ID 03-022)	Screening/Randomization			Foothills Medical Centre	20465	2021-09-15
<a href="#">5374-30</a> (Participant ID 17-013)	Screening/Randomization			University of Vermont Medical Center	20486	2021-09-16
<a href="#">5372-5</a> (Participant ID 15-004)	Screening/Randomization			Sunnybrook Health Sciences Centre	20443	2021-09-17
<a href="#">5362-172</a> (Participant ID 05-035)	Screening/Randomization			South Health Campus	20480	2021-09-18
<a href="#">5360-67</a> (Participant ID 03-023)	Screening/Randomization			Foothills Medical Centre	20471	2021-09-22
<a href="#">5360-68</a> (Participant ID 03-024)	Screening/Randomization			Foothills Medical Centre	20468	2021-09-24

## **PERK 2 Trial Management Group Meeting #21**

July 26<sup>th</sup>, 2021, 1:00pm-2:00pm MDT

**Attendees:** Ayoola Ademola, Kelcie Witges, Brenna Mattiello, Christine Churchill, Kelly Trask, Katrina Munro, Katie McIlquham, Liane Jean, Lynn Vicente, Alicia Alvarez, Monica Kunz, Melissa Cuke, Taylor Stranaghan and Gerardo Duque

**Regrets:** Dr. Kevin Hildebrand, Melanie Dodd-Moher, Kyrsten Payne, Zafeiria Glaris, and Joshua Rudnicki

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Meeting start: 1:00 pm MDT

### **1. Current Site Statistics**

- a. Screened 607 patients total - 207 were eligible to participate and 134 were recruited into the trial
- b. 68 Adverse Events total - 54 were mild and 14 were moderate
  - i. The severity of the AE is also determined by how it affects the participant's quality of living (e.g. A cast change in the ER due to significant discomfort would be moderate, even if pain is mild)
- c. 8 Serious Adverse Events total
  - i. Please inform coordinating team as soon as possible if an AE leads to a new hospitalization, reoperation, extension of current hospitalization, or any reports of life threatening event

### **2. Adverse Event Logs**

- a. Documentation to help sites keep track on any adverse events throughout the 0-7 week timeframe
- b. This log will be requested on a monthly basis to keep track of AE's across all sites
- c. AE's reported outside of 7 day treatment window will only be reported if they are an SAE
- d. **Request for AE Logs will be sent out this Friday, July 30, 2021**

### **3. Invoicing/Payment Procedures**

- a. All sites have now received an itemized data breakdown based on queries/data obtained by June 1, 2021
- b. Currently, we have completed payments for most sites (please let the Coordinating Centre know if this has not been completed)

- c. Payments will occur in milestones:
  - i. Enrollment & operative procedures
  - ii. Up to and including 12 weeks
  - iii. Up to and including 52 weeks
- d. Commonly missed data points:
  - i. Pre-operative radiographs
  - ii. Post-operative radiographs (we do accept fluoro images or intra-operative radiographs as well)
  - iii. Remote range of motion photos (we only require extension and flexion measurements)

#### 4. PERK 2: Protocol Deviation Logs

- a. No protocol deviations have been requested throughout the time of COVID-19 (only protocol violations)
- b. Sites need to document and report any protocol deviations that resulted from COVID-19 and any restrictions keeping the participant from completing visit data
  - i. The most common protocol deviations include:
    - 1. missed visits;
    - 2. visits collected out of the window; or
    - 3. missed data
- c. Coordinating Centre can send you a list of protocol deviations observed from REDCap data for your review
- d. **Current CRF has an error (6 week window is +/- 1 week and NOT +/- 2 weeks)**
  - i. **If you have done 6 week window visits outside of 1 week window, this has to be entered into your Protocol Deviation log**

#### 5. PERK 2 Trial Withdrawals

- a. Participants may be withdrawing from the PERK 2 trial in the following ways:
  - i. **Full Withdrawal** - No use of any data
  - ii. **Partial Withdrawal** - Stop drug, continue follow up and collect data
  - iii. **Partial Withdrawal** - Stop drug and follow up visits, allow continued data collection via chart reviews
  - iv. **Partial Withdrawal** - Stop drug, follow up visits and future data collection. Allow previously collected data to be used
- b. Site research staff must document all information surrounding the purpose and type of participant withdrawal and report in REDCap

## 6. PERK 2 Imaging: CIPAC and DICOM

- a. Primary issues from sites pertaining to PERK 2 imaging include:
  - i. Sites cannot obtain DICOM images
  - ii. Sites are unable to de-identify their DICOM images
  - iii. Sites require payments to be able to receive these DICOM images
- b. Most sites have been able to find a solution contacting CIPAC directly or their local diagnostic imaging department.
  - i. Please contact CIPAC with your questions: [cipac.centre@ucalgary.ca](mailto:cipac.centre@ucalgary.ca)
- c. **Sunnybrook Health and Sciences Centre has contacted local diagnostic imaging center and they can only provide DVD's with images per participant for \$50. We are unable to provide additional funds to cover these, so coordinating center will be working with site to find a solution.**

## 7. PERK 2 Trial Extension of 7 Day Enrolment Window

- a. After much deliberation with our team, we have decided not to extend our 7-day enrollment window at this time. We will keep you informed if further information/discussions on this topic occur with other stakeholders in the coming months.

## 8. Questions discussed during meeting

- a. *When a medication has been discontinued (i.e. the day of the phone call or the day or two prior) what would be the preference for entry of that discontinued medication? Would you enter it if it was ingested within the given window, or only if it was still being taken at time of phone call?*
  - i. Yes, we would report if the patient had taken the medication in the past week even though at the time of the phone call they had discontinued the medication.

### Overall Action Items:

- Complete PERK 2 – Protocol Deviation log to include all COVID-19 deviations
  - Check with local REB if these need to be reported
  - Send finalized/signed Protocol Deviation log to coordinating centre for filing
- Updated AE logs, have QI review and sign, and send to coordinating center
- Review your list of **outstanding research credentials** for local staff and send updated documents to the coordinating center

Meeting adjourned: 1:30 pm MDT

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**Next TMG Meeting:** Monday, August 30, 2021 at 1:00 pm MDT

## PERK 2 Trial Management Group Meeting #22

Aug 30<sup>th</sup>, 2021, 1:00pm-2:00pm MDT

**Attendees:** Dr. Kevin Hildebrand, Ayoola Ademola, Kelcie Witges, Brenna Mattiello, Christine Churchill, Kyrsten Payne, Melanie Dodd-Moher, Anelise Silveira, Alicia Alvarez, Zafeiria Glaris, Melissa Cuke, Taylor Stranaghan and Gerardo Duque

**Regrets:** Joshua Rudnicki, Kelly Trask, Katrina Munro, Katie McIlquham, Lynn Vincent, and Monica Kunz

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Meeting start: 1:00 pm MDT

### 1. Participant Data Entry

- a. We require data to be entered into REDCap as soon as possible
- b. Our data monitoring regulatory meetings rely heavily on this data
- c. Query responses are required for statistical analysis
- d. Enter all safety data (AE's and SAE's) into REDCap and address any concerns with the Coordinating Center as soon as you become aware
- e. The query report will be sent out on Wednesday, September 1<sup>st</sup>

### 2. Adverse Event Logs

- a. Documentation to help sites keep track of any adverse events throughout the 0-7 week timeframe
- b. This log will be requested at the end of every month
- c. Logs are needed to have printed proof of Adverse Events observed at your site

### 3. Pill Bottles and Pill Counts

- a. Expected pill counts:
  - i. At the 2-week visit, participants should have roughly 56 pills remaining
  - ii. At the 6-week visit, participant should have roughly 0 pills remaining
- b. Anything significantly over this amount should be addressed with the participant and reported into REDCap
- c. Misplaced pill bottles: require a **note to file** to document what occurred
  - i. This note to file is to be sent to your pharmacy team and filed in your participant's binder
- d. If participant forgets to bring pill bottle to visit, call them afterwards to get a pill count

- e. Pill bottle returns: Remind participants to return their pill bottle to every follow up visit (between 0-7 weeks) by adding a sticker to the top and/or reminding participant during phone call visits

#### **4. Participant Screening**

- a. All screen fails must be entered into REDCap with a reason for exclusion
- b. Screen fails occur if you approach participants for PERK 2 trial and exclude them based on eligibility criteria
- c. You have the option to document a reason at the bottom for not wanting to be part of the trial on the REDCap screening form. Click “yes” for exclusion for all exclusion criteria, including number 16 (unwilling to consent) and enter the information in the area that shows below

#### **5. Invoicing/Payment Procedures**

- a. All sites have now received an itemized breakdown of the current data collected, outstanding queries, and payments
- b. Payments will occur in milestones:
  - i. Enrollment & operative procedures
  - ii. Up to and including 12 weeks
  - iii. Up to and including 52 weeks
- c. Commonly missed data points:
  - i. Pre-operative radiographs
  - ii. Post-operative radiographs (we do accept fluoro images or intra-operative radiographs as well)
  - iii. Remote range of motion photos (we only require extension and flexion measurements)
- d. At this time, all sites who have sent invoices have been paid

#### **6. AE and SAE Review**

- a. Enter all safety data into REDCap
- b. AE logs must be kept up to date and sent to Coordinating Center at the end of every month
- c. #1 AE reported: sedation/drowsiness/fatigue
  - i. It’s helpful to ask participant when they were experiencing sedation/drowsiness/fatigue (i.e. before or after taking their trial medication)
  - ii. If a participant states they are experiencing “fatigue”, please request further information to confirm their symptoms. If “fatigue” is the report, please enter as “Other Complication” under Adverse Events

## 7. Remote Monitor Follow-Up

- a. Remote follow-up visits will be initiated when 4 participants have been randomized and at least 1 participant has completed their 12 week follow-up visit
- b. 5 sites have completed their remote follow-up visit at this time
- c. Upcoming visits with 2 sites in the upcoming month
- d. If your site has any questions/concerns about this, we can set up a 30 minute meeting for monitor training

### **Overall Action Items:**

- Address and respond to all queries on REDCap as soon as possible
- Update AE logs, have QI review and sign, and send to Coordinating Center
- Review your list of **outstanding research credentials** for local staff and send updated documents to the coordinating center

Meeting adjourned 1:40 pm MDT

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**Next TMG Meeting:** Monday, September 20, 2021 at 1:00 pm MDT (12:00pm PDT and 3:00pm EDT)

## **PERK 2 Trial Management Group Meeting #23**

September 20<sup>th</sup>, 2021, 1:00pm-2:00pm MDT

**Attendees:** Dr. Kevin Hildebrand, Kelcie Witges, Brenna Mattiello, Kelly Trask, Juliette Sweeney, Christine Schemitsch, Melanie Dodd-Moher, Katie McIlquham, Anelise Silveira, Alicia Alvarez, Zafeiria Glaris, Taylor Stranaghan and Gerardo Duque.

**Regrets:** Ayoola Ademola, Joshua Rudnicki, Monica Kunz, Melissa Cuke, Kyrsten Payne, Christine Churchill, Katrina Munro, and Ryan Khan.

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Meeting start: 1:00 pm MDT

### **1. PERK2 1 Year No Cost Extension**

- a. This project will be extended until September 30<sup>th</sup>, 2022 for recruitment, along with an additional year of follow-up visits
- b. This extension will not affect anything regarding recruitment/randomization or follow up at this time

### **2. Upcoming Drug Shipment**

- a. This batch will arrive at each site before October 18<sup>th</sup>, 2021 to cover all drugs that will expire on this date
- b. We will be in contact with your site once this next drug shipment occurs

### **3. COVID-19 Wave #4**

- a. Calgary and Edmonton sites have postponed all elective surgeries at this time
- b. No changes to report at any other hospital
- c. Fractures continue to be treated and PERK2 will not be impacted in the area about COVID restrictions

### **4. Approaching to Consent and Enrollment Success**

- a. Common reasons eligible patients refuse to consent to the trial
  - i. Risks associated with the drug (sedation, nausea, etc.)
  - ii. Apprehensions about the drug not being approved by FDA for this indication
  - iii. Patients refusing to take medication due to concern about mixing their medications
  - iv. Patients refusing to use two effective methods of contraception

- b.** Helpful solutions:
  - i.** Encouraging more involvement of the clinical team (i.e. allowing the treating surgeon or residents to provide more information about the trial prior to consenting)
  - ii.** Providing ongoing PERK 2 updates to clinical team
  - iii.** Address the use of Ketotifen as a safe indication that is also FDA approved for pediatric children with asthma

## **5. Invoicing/Payment Procedures**

- a.** All sites have now received an itemized breakdown of the current data collected, outstanding queries, and payments
- b.** Payments will occur in milestones:
  - i.** Enrollment & operative procedures
  - ii.** Up to and including 12 weeks
  - iii.** Up to and including 52 weeks
- c.** Commonly missed data points:
  - i.** Pre-operative radiographs
  - ii.** Post-operative radiographs (we do accept fluoro images or intra-operative radiographs as well)
  - iii.** Remote range of motion photos (we only require extension and flexion measurements)
- d.** At this time, all sites who have sent invoices have been paid

## **6. Adverse Events/Serious Adverse Events**

- a.** Currently, we have 79 AE's reported
  - i.** 62 mild
  - ii.** 16 moderate
  - iii.** 1 severe
- b.** Grading of AE's: review with PI or QI and confirm if the event should be reported as a Serious Adverse Event
- c.** All SAE's must be reported with 48 hours after becoming aware of event and will be tracked throughout the trial (0 to 52 weeks)
- d.** Most common SAE: an event that results in a prolonged hospitalization visit

**Overall Action Items:**

- Update AE logs, have QI review and sign, and send to Coordinating Center
- Review your list of **outstanding research credentials** for local staff and send updated documents to the coordinating center

Meeting adjourned 1:50 pm MDT

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**Next TMG Meeting:** Monday, October 25 2021 at 1:00 pm MDT (12:00pm PDT and 3:00pm EDT)



PERK 2 Trial Steering Committee  
Meeting #7  
September 13, 2021, 5:30 – 7:00pm MDT

**Attendees:**

Dr. Nicholas Mohtadi – Chair/Clinical Trialist  
Dr. Kevin Hildebrand – Chief Investigator  
Dr. Neil White – Site Principal Investigator, South Health Campus  
Dr. Michael Bosse – Sponsor’s Medical Expert  
Gerardo “Gerry” Duque, MA – Clinical Trials Unit, Facilitator

**Regrets:**

Monica Kunz, CCRP – Senior Clinical Research Coordinator, Sunnybrook Health Science Center  
Dr. Tolulope Sajobi – Biostatistician

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**Meeting called to order:** 5:35 pm MDT

**Review of June 14<sup>th</sup>, 2021 minutes**

- No concerns/changes to previous meeting minutes reported by members
- Members did not request to add any agenda items to this meeting

**Additional Agenda Items**

- ***Monica Kunz, CCRP position within the Trial Steering Committee (TSC)***
  - Monica will be unable to continue her position with the TSC due to personal reasons. She suggested the possibility of taking a leave of absence until she is able to come back.
  - Dr. Hildebrand proposed offering a leave of absence to Monica, and adding another member to the TSC in the interim. Monica is welcome to come back to the committee when possible.
  - The committee offers their support and sympathy to Monica during this time.
  - The committee agrees with moving forward inviting a new member in the same role as a Trial Management Group representative from an active site.
  - Dr. Hildebrand nominated the following people to be added to the TSC:
    - Kelly Trask – Research Manager at Queen Elizabeth II Health Science Center
    - Katie McIlqham – Research Coordinator at The Ottawa Hospital – General Campus
    - Melissa Cuke – Research Coordinator at The University of Vermont Medical Center

# PERK 2

- **Action Item:**
  - Dr. Hildebrand and Gerry will approach to confirm interest.
- **Extending enrollment window beyond 7 days (Dr. White)**
  - Following up on our previous discussion, where do we stand on possibly extending the enrollment window beyond 7 days. This could help increase our enrollment.
  - Since the June 14, 2021 meeting, we brought this to the TMG to check if this change would lead to increased recruitment. Site coordinators confirmed that this usually not the case for their sites. By the time they hear of patients being outside of the 7-day injury window, they are also non-operative.
  - **This topic will continue to be in consideration as a possible next step if data analyses show that a significant improvement in enrollment, aided by protocol changes, is necessary.**

## Trial Steering Committee Report #7 Review

- **Current enrollment success at low recruiting sites**
  - Carolinas Medical Center in Charlotte, NC: At a 10% success rate, it is our site with the lowest recruitment success percentage. Coordinating center team plans on meeting with the local team to discuss this issue and offer retraining, or other input that could lead to improved enrollment.
  - The Ottawa Hospital – General and Civic sites in Ottawa, ON: Local coordinators are meeting all PERK 2 surgeons in October for retraining. Surgeon engagement is an issue at the sites, so they want to get better communication with them in regards to participant prospects.
  - Queen Elizabeth II Health Sciences Center – Halifax, NS: Site does not see many screens coming in, and these rates show early unsuccessful attempts. Site has increased their success rate in the last year, enrolling most participants approached. We expect an improvement as they approach more participants in the coming year.
- **Adverse Event (AE) and Serious Adverse Event (SAE) reporting for events unrelated to PERK 2 IP/Placebo (Dr. Mohtadi)**
  - A kidney stone removal, a spinal fusion, and a compartment syndrome were reported, but they are clearly unrelated to being involved in the trial. It may be unnecessary to keep reporting these events.
  - AE's and SAE's should be reported if they happen within the 7-week treatment period. All events listed above happened during treatment window.

# PERK 2

- However, reporting serious adverse events (leading to a threat to life, hospitalization, or prolonging hospitalization) through the time of the trial is necessary for regulatory purposes.
- **A note regarding relatedness to the trial will be added to future AE/SAE reports.**

## **Department of Defense (DoD) extension/funding responses**

- Coordinating team submitted “no cost extension” forms to the DoD on July 1, 2021, as per their request.
- Grants officer confirmed receipt and need for financial form SF425 on August 26, 2021. University of Calgary Research Finance office was engaged to finalize the report. UofC Research Finance office completed the report on September 2, 2021.
- Form SF425 was submitted to the DoD by our team on September 2, 2021. We did not receive a confirmation of receipt from the DoD. Team is sending weekly follow up emails to grants officer.

## **Data Monitoring Committee (DMC) Meetings**

- DMC Introductory Meeting occurred August 9, 2021. Three issues were identified at this meeting:
  - ***Re-calculating the trial’s sample size and clarifying the meaning of “non-functional range of motion” and whether there is a need for an independent statistician who could be unblinded as part of a data adjudication team.***
    - Protocol presents that non-functional ROM is <30-130. Sample size is based upon mean group differences between the three groups as determined between baseline and 12-week ROM measures. This was based on the PERK-1 trial in the operative group.
    - Dr. White will provide the email of an independent statistician that works running these types of trial reviews
    - A lengthy discussion followed, and it was determined that this will be taken offline as described below.
  - **Dr. Mohtadi, Dr. Hildebrand, and Gerry will meet with Dr. Sajobi to discuss these topics and finalize our understanding prior to going back to the DMC for their first official meeting**

**Meeting adjourned** 6:58pm MDT

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**Next TSC meeting:** Monday, December 13<sup>th</sup>, 2021 at 5:30pm – 7:00pm MDT



**PERK 2 Data Monitoring Committee (DMC)**  
Introductory Open Meeting  
August 9, 2021, 9:00 – 10:00am MDT

**Attendees:**

Dr. Nicholas Mohtadi – Trial Steering Committee Chair  
Dr. Kevin Hildebrand – Trial Principal Investigator  
Dr. James Wright – Data Monitoring Committee Chair  
Dr. Kim Madden – Trial Methodologist  
Dr. Saam Morshed – Orthopaedic Surgeon/Epidemiologist  
Dr. Helen Razmjou – Advanced Practice PT  
Gerardo “Gerry” Duque, MA – Clinical Trials Unit, Facilitator

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**Meeting called to order** – 9:00am MDT

**1. Conflict of Interest declaration**

- a. No COI was declared. Data monitoring committee members need to send their signed conflict of interest forms to Gerry. Gerry will follow up with members later in the week to finalize documentation.

**2. Review of DMC charter**

- a. **Comment #1:** DMC meetings start sometime in the first year of a trial, but we are currently at year 4.
  - i. Due to contract, regulatory, and database delays, the official start date for the PERK 2 trial was in June 2019. This was almost 2 years after the contractual start date of September 30, 2017. Additionally, COVID-19 posed significant delays during 2020 and part of 2021.
- b. **Comment #2:** Trial-stopping triggers related to serious adverse events that are life threatening or cause death should occur prior to DMC running a formal interim analysis.
  - i. Trial Steering Committee (TSC) will notify DMC as soon as it occurs to discuss next steps.

# PER 2

- c. **Comment #3**: Page 6 of the DMC charter states, “No formal interim statistical analyses of the primary outcome measure are planned”.
    - i. An outline of the interim analysis plan and procedures is in the protocol and team will consider this issue. In addition, trial statistician, Dr. Tolulope Sajobi, is to be present in future meetings to address questions related to statistical plans for the trial.
3. **Open/Closed report definitions and review**
- a. **Comment #1**: Clarity about the one adverse even.
    - i. This report refers to a participant experiencing suicidal ideation while in the trial. Participant stopped all medications provided at discharge, including trial IP/placebo. These symptoms have now resolved. Local PI graded the event as “severe”, and not a serious adverse event, as it did not lead to hospitalization or further treatments apart from discontinuing medications.
  - b. **Comment #2**: Clarity on the trial outcomes. On trial stopping rule #3 (*See page 9 of DMC Intro Report*) a non-functional range of motion (ROM) is reported as being between 30 to 130 degrees, but this arc is within the functional ROM category. Also, clarify the primary outcome, is it a dichotomous (Non-functional vs. Functional) or continuous (ROM) measure?
    - i. The primary outcome measure is continuous. It refers to a difference between ROM measurements at baseline and 12 week.
    - ii. The dichotomous aspect is a secondary outcome.
    - iii. Trial stopping rules is based on safety between groups.
    - iv. Team will revisit the interim stopping rule for clarity.
  - c. **Comment #3**: Table 1 presents enrollment success percentages, with some at 100% success and some with very low success rates.
    - i. The sites in questions started recruitment efforts in the last two months. Coordinating center is working with them to address issues with recruitment procedures, and accurate reporting of screening/enrollment data.

# PER 2

- d. **Comment #4:** Additions to open report:
  - i. Table related to screening/enrollment eligibility based on common inclusion/exclusion characteristics to address generalizability.
  - ii. Table with overall outcome rates.
  
- e. **Comment #5:** Data completion in Table 2
  - i. Data completion refers to percent of data completed/obtained for the participants that have reached that specific trial milestone. This is sensitive to outstanding queries and data missed.
  - ii. Gerry to add a column of completion percent of primary outcome to reflect a better idea of data integrity for use in final analyses.
  
- f. **Comment #6:** In reference to the last line on page 10: “Currently we are awaiting a no cost extension for the trial that would make it possible to reach close to 350 recruits total”. This is well below the expected recruitment of 702 participants.
  - i. Contract ends September 29, 2021 and we are awaiting response for one year no cost extension from the US Department of Defense. We offered a few scenarios for the upcoming year, and getting to 350 total recruitments is attainable with our current budget.
  - ii. Gerry to add “Needed vs. Actual” view of recruitment rates to future reports.
  - iii. The PERK 2 TSC discussed options to change certain inclusion/exclusion criteria to increase recruitment (i.e. extending injury/first dose time, and including non-operative patients).

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## 4. **DMC Closed session, report, and statistician presence**

- a. Characteristics of a closed report for future sessions would include baseline data, adverse events, and outcomes separated by treatment groups. In addition, a statistician joins the meeting to help review the report and discuss subsequent analyses resulting from the meeting. This person could be the trial statistician or an outside statistician unrelated to the trial.
  - i. DMC members should stay blinded, but certain data, like adverse events, separated by groups could signal what may be the treatment groups. Trial statistician would be in the same position than the rest of the DMC members (i.e. only know Group A vs Group B).
  - ii. Un-blinding may be necessary (safety issues), which could lead to the trial statistician being un-blinded.
  - iii. Identify another statistician as a good contingency plan to have to avoid the trial statistician being un-blinded.

## 5. **Next meeting and resolution of discussed recommendations**

- a. Dr. Kevin Hildebrand will engage trial statistician, Dr. Tolulope Sajobi, to discuss the deliberations discussed above.
- b. Gerry to bolster report by adding the tables/figures recommended by the committee. Team to use report recommendations to build a final format for future Open/Closed reports.
- c. A preliminary September meeting was proposed. Possibly **Monday, September 13, 2021**.

**Meeting adjourned** – 10:00am MDT

# PERK 2 TRIAL NEWSLETTER



Dr. Kevin A. Hildebrand

July 2021 Edition, Vol. 1

## GOALS

By July 30:

- Reach 140 total recruitments for the trial
- Complete Protocol v6.0 amendments
- Complete pharmacy/participant payments for active sites
- Have 16 sites screening/recruiting

## MILESTONES

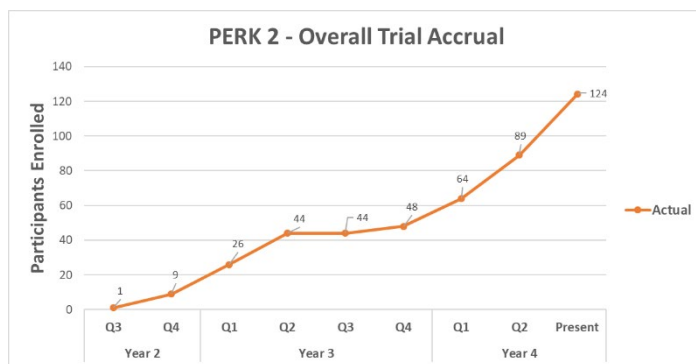


### Current Overall Enrollment Status:

Peter Lougheed Centre (n=28)  
South Health Campus (n=27)  
Foothills Medical Centre (n=15)  
Sturgeon Community Hospital (n=14)  
University of Vermont Medical Center (n=10)  
University of Maryland Medical Center (n=9)  
The Ottawa Hospital, General Campus (n=7)  
St. Paul's Hospital (n=4)  
Sunnybrook HSC (n=3)  
The Ottawa Hospital, Civic Campus (n=2)  
St. Michael's Hospital (n=2)  
Queen Elizabeth II HSC (n=2)  
Carolinas Medical Center (n=1)  
St. Joseph's Hospital (n=0)

### JUNE 2021 Enrollment Hall of Fame:

1. University of Vermont Medical Center (n=5)
2. South Health Campus (n=4)
3. Foothills Medical Centre (n=3)
4. Sturgeon Community Hospital (n=2)
5. Peter Lougheed Centre (n=1)
6. St. Paul's Hospital (n=1)



## TRIAL UPDATES

- With **16 participants** enrolled in **June**, we have reached 124 participants! **This makes June 2021 our highest enrolling month since trial start. Thank you all for your efforts!**
- **Royal Columbian Hospital (RCH)** has started PERK 2 activities. **Welcome to the trial RCH!** There are now 15 site screening/enrolling!
- The next **Trial Management Group** meeting with active sites proposed for **Monday, July 26, 2021 at 1:00pm MDT (12:00pm PDT, 3:00pm EDT).**

## PERK 2 TEAM

**Trial PI/Sponsor:** Kevin Hildebrand 403-220-7282  
**Research Coordinator:** Gerardo Duque 403-943-5556  
**Research Assistant:** Taylor Stranaghan 403-943-5537

# PERK 2 TRIAL NEWSLETTER



Dr. Kevin A. Hildebrand

August 2021 Edition, Vol. 1

## GOALS

By August 31:

- Reach 150 total recruitments for the trial
- Complete pharmacy/participant payments for active sites
- Have 16 sites screening/recruiting

## MILESTONES

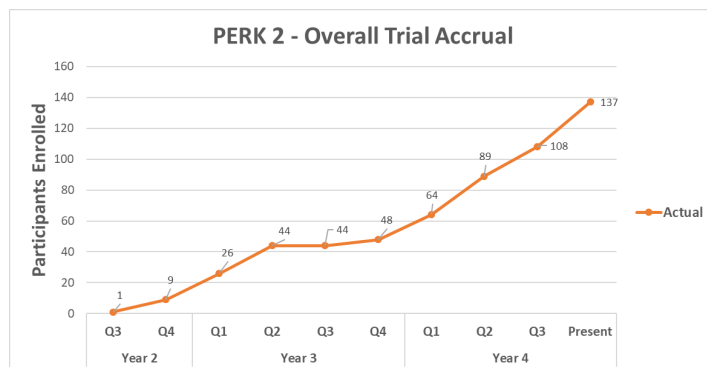
### Current Overall Enrollment Status:

South Health Campus (n=30)  
Peter Lougheed Centre (n=28)  
Foothills Medical Centre (n=17)  
Sturgeon Community Hospital (n=15)  
University of Vermont Medical Center (n=10)  
University of Maryland Medical Center (n=10)  
The Ottawa Hospital, General Campus (n=8)  
St. Paul's Hospital (n=4)  
Sunnybrook HSC (n=3)  
St. Michael's Hospital (n=3)  
Queen Elizabeth II HSC (n=3)  
Royal Columbian Hospital (n=2)  
The Ottawa Hospital, Civic Campus (n=2)  
Carolinas Medical Center (n=1)  
St. Joseph's Hospital (n=1)



### JULY 2021 Enrollment Hall of Fame:

1. South Health Campus (n=3)
2. Royal Columbian Hospital (n=2)
3. Sturgeon Community Hospital (n=2)
4. Foothills Medical Centre (n=1)
5. University of Maryland (n=1)
6. St. Joseph's Hospital (n=1)
7. St. Michael's Hospital (n=1)
8. Queen Elizabeth II HSC (n=1)
9. The Ottawa Hospital, General (n=1)



## TRIAL UPDATES

- With **13 participants** enrolled in **July**, we have reached 137 participants!
- **Royal Columbian Hospital (RCH)** and **Saint Joseph's Hospital (SJH)** teams recruited their first participants. All current PERK 2 sites have active participants! Thank you all.
- The next **Trial Management Group** meeting with active sites proposed for **Monday, August 30, 2021 at 1:00pm MDT (12:00pm PDT, 3:00pm EDT)**.

## PERK 2 TEAM

**Trial PI/Sponsor:** Kevin Hildebrand 403-220-7282  
**Research Coordinator:** Gerardo Duque 403-943-5556  
**Research Assistant:** Taylor Stranaghan 403-943-5537

# PERK 2 TRIAL NEWSLETTER



Dr. Kevin A. Hildebrand

September 2021 Edition

## GOALS

By September 30:

- Reach 170 total recruitments for the trial
- Complete pharmacy/participant payments for active sites
- Have 16 sites screening/recruiting

## MILESTONES

### Current Overall Enrollment Status:

South Health Campus (n=32)  
Peter Lougheed Centre (n=30)  
Foothills Medical Centre (n=18)  
Sturgeon Community Hospital (n=15)  
University of Vermont Medical Center (n=11)  
University of Maryland Medical Center (n=11)  
The Ottawa Hospital, General Campus (n=8)  
Royal Columbian Hospital (n=5)  
St. Paul's Hospital (n=4)  
St. Michael's Hospital (n=4)  
Sunnybrook HSC (n=3)  
Queen Elizabeth II HSC (n=3)  
The Ottawa Hospital, Civic Campus (n=2)  
St. Joseph's Hospital (n=2)  
Carolinas Medical Center (n=1)



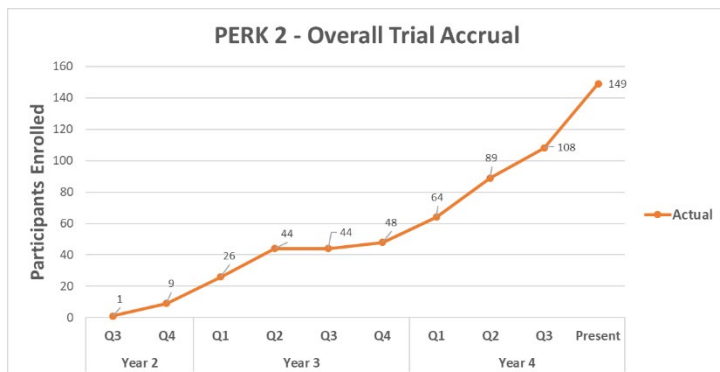
### AUGUST 2021 Enrollment Hall of Fame:

1. Royal Columbian Hospital (n=3)
2. Peter Lougheed Centre (n=2)
3. South Health Campus (n=2)
4. Foothills Medical Centre (n=1)
5. St. Joseph's Hospital (n=1)
6. St. Michael's Hospital (n=1)
7. The University of Vermont MC (n=1)
8. University of Maryland MC (n=1)



## TRIAL UPDATES

- With **12 participants** enrolled in **August**, we have reached 149 participants!
- **McGill University Health Center** has been approved by all regulatory agencies to begin PERK 2 enrollment. All PERK 2 sites have now received regulatory approval.
- The next **Trial Management Group** meeting with active sites proposed for **Monday, September 20, 2021 at 1:00pm MDT (12:00pm PDT, 3:00pm EDT)**.



## PERK 2 TEAM

**Trial PI/Sponsor:** Kevin Hildebrand 403-220-7282  
**Research Coordinator:** Gerardo Duque 403-943-5556  
**Research Assistant:** Taylor Stranaghan 403-943-5537



## CERTIFICATE OF COMPLETION

This certificate is awarded to

**Gerardo Duque**

on June 10, 2021 for successful completion of the

### **Leadership in Patient-Oriented Research: Pragmatic Clinical Trials Certificate**

*This certificate is an Accredited Group Learning Activity (Section 1) as recognized by the Royal College of Physicians and Surgeons of Canada and approved by the University of Calgary Office of Continuing Medical Education and Professional Development. Participants can claim up to a maximum of 53 study credits.*

*Participants are asked to claim the actual number of hours attended: Gerardo Duque attended \_\_\_\_ hours.*

Dr. Dean Eurich

Joint Lead, Career Development Platform

Dr. Marilynne Hebert

Joint Lead, Career Development Platform

Dr. Michael Hill

Joint Lead, Pragmatic Clinical Trials Platform

Dr. Lawrence Richer

Joint Lead, Pragmatic Clinical Trials Platform

