Participant Information Sheet and Consent Form

TITLE:	mymobility™ Clinical Study: A Prospective Multicenter Longitudinal Cohort Study of the mymobility Platform
PROTOCOL NO.:	CLU2018-13CH
SPONSOR:	Accelero Health Partners, LLC (A Zimmer Biomet Company)
INVESTIGATOR:	Dr Camdon Fary Epworth HealthCare SOS Clinic, 166 Gipps Street, VIC 3002
STUDY-RELATED PHONE NUMBER(S):	Name: Stasie Abela (Clinical Research Nurse) Number: 03 9936 8205
HREC NUMBER:	2019-09-822-AA
LOCAL STUDY NUMBER:	EH 2019-452

Part 1

Introduction

You are being invited to take part in a research study. A person who takes part in a research study is called a research participant.

What should I know about the consent process?

- Someone will explain the research to you.
- This form sums up that explanation.
- Whether you take part is up to you.
  - Taking part in research is voluntary.
- You can choose not to take part.
  - There will be no penalty or loss of benefits to which you are otherwise entitled.
  - The quality of care you receive will not be affected by choosing not to participate.
- You can agree to take part and later change your mind.
- Ask all the questions you want before you decide to participate.
- You may talk about this study with family or friends before you decide to participate.
- You will be given a copy of the consent form.
- A sub-study is being undertaken to study electronic consent methods (animation with an electronic *Patient Information and Consent Form*) compared to reading this document. You will

be randomized to either group for this sub-study and asked to complete a small survey with research staff about your understanding of the Zimmer mymobility project. If you decline to participate in the consent sub-study, you may still participate in the Zimmer mymobility project and this will not impact your participation in the Zimmer mymobility study or your surgery.

Why is this research being done?

The purpose of this research is to determine if education and exercise for joint replacement surgery remotely guided by the mymobility mobile telehealth application (mymobility application or app) paired with the Apple Watch (smartwatch) is just as good, or better, than current standard education and outpatient physical therapy after joint replacement.

You were selected as a possible research participant because you are scheduled for a joint replacement surgery with a Zimmer Biomet device as part of your clinical care (partial or total knee replacement or a total hip replacement), which usually involves outpatient post-operative physical therapy.

There are three different parts to this study. If you choose to participate, you will be enrolled in the **third** part of the study which is described below.

The third part of the study will collect data from a large number of participants (10,000 globally) across a number of hospitals and research centres. There will be up to 700 patients recruited from 2 sites in Australia.

The data being collected includes information about your surgical procedure, what sort of physiotherapy you receive, your experience with the mymobility App and smartwatch, and your activity levels as captured through the wearing of the apple watch. In addition, your doctor's routine clinical assessments of your recovery following surgery will be collected.

This data will be analysed to try to determine if certain information collected about you by the mymobility app, smartphone and smartwatch during the study is related to patient outcomes after joint replacement. This information will provide real-world data which may be used for future product improvements. It also may help to provide a guideline for optimal patient recovery following arthroplasty procedures.

How long will I be in this research?

Your participation in this study will last 13 -17 months.

What happens to me if I agree to take part in this research?

After all of your questions are answered to your liking, you will be asked to sign and date this consent form. After you sign and date the form the study procedures will begin as described below:

Before your surgery

- You will be asked to provide your email address for registration on the mymobility app and a unique study identification number will be created for you.

- If you do not already own an Apple Watch (Series 3 or newer), you will be provided one at this time to use in the study. You will also be given access to other material to help you learn how to use the study smartwatch.
- The study team will help you download the mymobility app to your iPhone (iPhone 6 or newer). If you have an iPhone 7 or newer, the study team will also help you download the Health & Fitness Recorder App. This may include:
  - Ensuring the operating system on your phone is current
  - Ensuring the proper types of data are being collected by the HealthKit application on your iPhone
  - Reviewing instructions for use of the smartwatch, including pairing with your iPhone, charging, looking at the various information displays, and setting alerts
- Additionally, the study team may collect information about how long it takes to set up the mymobility application on your phone and review instructions for the proper use of the application and study smartwatch.

  If you do not own an Apple iPhone, will will not be eligible to participate in this study. Your doctor will follow his routine program for post surgical rehabilitation and physiotherapy.

In addition to the normal questionnaires that your doctor will ask you to complete, you will be asked to complete several questionnaires at various time periods during the study. These questionnaires will capture information about your health history, living status, daily activities, your general health, any pain you may have, and your satisfaction and experience with the mymobility app and smartwatch. The questionnaires will also collect information about other medical appointments (including physiotherapy), if needed, besides those provided by your doctor.

During the time after your pre-operative visit but **before** your surgery, you will be prompted to review educational content and complete surveys on the mymobility app. In addition, you will be guided through exercises recommended for you by your surgeon to prepare for your surgery. The study team will ask you to wear the smartwatch except when it is charging (preferably at night time while you sleep). In addition, carrying your phone will give you more accurate distance during your workouts so we encourage you to carry your phone as much as you are comfortable. The study team will contact you during this period to confirm that you are using the app and the smartwatch as directed and are not having any problems. The study team can also answer any questions that you have about the mymobility app.

Your joint replacement procedure will be done as your doctor would normally perform the surgery.

After your surgery

The study team will ask you to wear the smartwatch except when it is charging (overnight while you sleep). In addition, carrying your phone will give you more accurate distance during your workouts and we encourage you to carry your phone as much as you are comfortable. The mymobility app will guide you through a scheduled education and exercise program you can do at home. You may or may not have any scheduled home physical therapy visits or home health visits. Please inform your doctor or care team if you participate in any formal, outpatient physical therapy. The study team may contact you after your surgery to be sure you are using the mymobility app and the smartwatch and see if you have any questions about the mymobility project. You can also send messages to your doctor's care

team using the mymobility app if you have questions about your recovery. Please note that this is not for medical advice or emergencies, but only for study related recovery/research questions

If you are sent to a nursing facility after your surgery, you will continue to use the mymobility app and wear the study smartwatch, but you should still follow all instructions for any physical therapy provided by the staff of the nursing facility. After you leave the nursing facility, you will continue to use the scheduled recovery program remotely guided by the mymobility app with limited or no assistance by outpatient physical therapy.

After your surgery, you will return to your doctor's office for follow-up visits as you would normally. Two of these visits should occur at about 30 days and 90 days after your surgery. At the time of these follow-up visits, you will also be asked to complete the questionnaires that are similar to the ones you completed before surgery. These questionnaires will ask you about your health, daily activities, and how your surgical joint is doing. You will also be asked about your satisfaction with your recovery experience. These questionnaires may be provided to you through the mymobility app, paper or the study electronic data collection program during your follow-up visits.

At your follow-up visits, your doctor will evaluate your progress after surgery. If you have been using the mymobility app and your doctor believes you might benefit from standard physical therapy, you may be asked to participate in some standard outpatient physical therapy. If you make sufficient progress with the additional standard physical therapy, you may be able to return to using only the mymobility app for your recovery program.

Your post-operative recovery program guided by the mymobility app will be complete by 12 weeks after your surgery, although additional rehab can be recommended by your doctor if needed. After the recovery program finishes, you should continue to wear the study smartwatch daily and keep the mymobility app active on your phone. You will continue to receive helpful information, guidance, and tips for your recovery throughout the duration of the study. At 6 months and 1 year after your surgery, you will receive similar surveys to complete. These questionnaires may be completed through the mymobility app or an email link to the study electronic data collection program.

After your 12-month surveys are complete, you participation is complete, and you will need to unregister the Apple Health & Fitness Recorder to discontinue its data collection and transmission. You may contact the study team for instructions on how to do this.

Below is a table which outlines when your visits will occur, and what will be required during each study visit:

Data Collection Activities	Pre-operative	1 month Post-operative	3 month Post-operative	6 Month Virtual Visit (at Home)	12 Month Virtual Visit (at Home)
Total Time	1 Hour 15 Minutes	45 Minutes	45 Minutes	15 Minutes	15 Minutes
Setting up the iPhone and watch	30 minutes				
Clinical Assessments with Surgeon	15 minutes	15 minutes	15 minutes		
Patient Questionnaire #1	15 minutes (via App)				
Patient Questionnaire #2		15 minutes (via App)			
Patient Questionnaire #3			15 minutes (via App)		
"Quality of Life" Questionnaire	5 minutes (via App)	5 minutes (via App)	5 minutes (via App)	5 minutes (via App)	5 minutes (via App)
Specific 'Hip' or 'Knee' Questionnaire	10 minutes (via App)	10 minutes (via App)	10 minutes (via App)	10 minutes (via App)	10 minutes (via App)

What are my responsibilities if I take part in this research?

If you choose to take part in this research, you agree to:

- Wear the study smartwatch provided to you throughout the entire duration of your participation, except when it is charging. Carry your smartphone with you and charge it daily.
- Complete the exercises and read the educational material assigned to you, whether through the mymobility app or standard methods.
- Attend all follow-up visits requested by your doctor.
- Complete all other activities assigned to you in the mymobility app or sent via mail or email (education, questionnaires, etc.).

Could taking part in this research hurt me?

Computer-based rehabilitation is already the standard of care at many institutions in the United States. The mymobility app is available to hospitals and physician practices in Australia outside of this study. The risks of participation in this study are similar to those normally associated with standard post-operative physical therapy. Some risks unique to the mymobility application include:

1. **Inadequate Recovery**
   It is possible that your recovery guided by the mymobility app will not progress as well as standard physical therapy. This risk is very low if you complete the activities and exercises as directed. In order to reduce this risk, your doctor will evaluate your progress at your follow-up visits and can recommend additional standard physical therapy if needed.

2. **Skin Irritation**
   The study smartwatch may cause a rash, sores, or other minor physical discomforts on the wrist.

3. **Privacy Breach**
   While methods will be put in place to protect the privacy of your health and identity (email address) information, these methods may fail, leading to your private health information or email address becoming available to others without your permission. Some data derived from your participation in this study will be sent overseas and the regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia.

4. **Other Risks**
   There may be unforeseen risks to you that we cannot predict.

   In addition, you will be answering questions about how you are feeling, and this includes whether you are experiencing any anxiety. If you answer this question with a reqponse that suggests you have severe anxiety, you will be contacted by your doctor.

Will it cost me money to take part in this research?

The cost of your standard medical treatment will be billed to you and your insurance company. This study has required procedures or examinations that are normally required of patients having joint replacement surgery. You will be responsible for any deductibles or applicable co-pays for routine

office visits and x-rays. You will not be charged for any visits related only to the study. The study smartwatch will be provided to you at no cost. If you do not undergo joint replacement surgery as planned or leave the study early, the smartwatch will need to be returned to your doctor.

Neither you nor your insurance company will have any additional financial obligations as a result of participating in the study.

This study is sponsored and funded by Accelero Health Partners, LLC, the company that distributes the mymobility App.

Your doctor will be receiving payments as a result of participating in this study. These payments are to provide adequate compensation to cover the time spent in conducting additional study activities outside of his routine patient management.

Will taking part in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this study. Possible benefits to you may include increased satisfaction with your surgical recovery experience and decreased costs to you and/or your insurance associated with office-based physical therapy. You will be provided an Apple Watch (smartwatch) for use in the study, which has many potential uses outside of tracking health information and pairing with the mymobility application. Information learned in this study may help the Sponsor and doctors learn more about the types of patients that may benefit the most from at home rehabilitation guided by applications such as the mymobility app.

What other choices do I have besides taking part in this research?

The alternative to participating in this research study is to complete post-operative outpatient rehabilitation according to the standard of care prescribed by your doctor. This may include other types of mobile application-guided rehab similar to mymobility; however, no study-specific data will be collected associated with your use of any such application.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the study team at the phone number listed above on the first page.

What if I am injured because of taking part in this study?

If you are injured as a result of your participation in this investigation you may be entitled to compensation.

Sponsors of clinical investigations in Australia have agreed that the guidelines developed by their industry body, Medical Technology Association of Australia (MTAA), will govern the way in which compensation claims from injured participants are managed by sponsors. The sponsor is obliged to follow these guidelines.

However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation.

These guidelines are available for your inspection on the MTAA website (www.mtaa.org.au) under Policy - Clinical Investigations. Alternatively, your study doctor can provide you with a hard-copy of the guidelines.

It is the recommendation of the independent ethics committee responsible for the review of this investigation that you seek independent legal advice before taking any steps towards compensation for injury.

Can I be removed from this study without my approval?

The person in charge of this study can remove you from participating without your approval. Possible reasons for removal include:

- On the day of your surgery, you no longer meet the requirements for participation in the study.
- It is in your best interest.
- The research is canceled by the Sponsor.
- You are unable to keep your scheduled appointments.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this study.

What happens if I agree to be in this study, but I change my mind later?

If you decide to participate, you are free to leave the study at any time. There will be no penalty of loss of benefits, nor will it interfere with your future care. If you decide to leave this study, contact the study team so that the investigator can:

- Document your withdrawal from the study.
- Make arrangements to ensure you are able to complete your physical therapy according to standard of care.
- Make arrangements for you to return the smartwatch, if one was lent to you.
- Provide you with instructions for unregistering the Apple Health & Fitness Recorder to discontinue its data collection and transmission.

Will I be paid for taking part in this research?

You will not be paid for your participation in this study. If you agree to participate in the study, and complete all study activities up to the 12 month follow up visit, you are able to keep the smartwatch at the end of the study.

However, if you choose to leave the study before the 12 month visit, or are no longer eligible to participate in the study, then you will need to return the smartwatch to the study site.

Authorization to Use and Disclose Information for Research Purposes

The study will gather certain personal information about you. This information will be held by Zimmer Biomet and its authorised representatives and will be non-identifiable. The sponsor will only identify you using a patient code, your year of birth, and your gender.

Your data will be stored in the United States for a period of 15 years and may be accessed by the following:

- Dr Fary and the study staff at Epworth HealthCare;
- Accelero Health Partners, LLC ("Research Sponsor"), and its authorized representatives and other researchers involved in this study. The Research Sponsor may, among other purposes, use your information to review the study and the study results and to conduct analysis on the data from the study, to publish results as noted below, and to use in its product development, design, and improvement activities; The Local Sponsor for this study is Zimmer Biomet Pty Ltd.
- Apple Inc., is providing apps from which the Research Sponsor may collect data from you. Apple may receive and use health information described in this consent and Authorization in its health and fitness research, product development, design, and improvement activities. This could include aggregating data from this study with data from other research studies sponsored by Apple. Apple will never receive any data that directly identifies you as part of the study operations and any data Apple receives as part of the study will not be combined with any data you may separately choose to provide to Apple as part of your use of Apple products or services, such as iTunes;

At the end of this storage period your data will be securely destroyed.

Your treating doctor/s will be notified of your participation in this study and the exchange of clinically relevant information noted by the trial doctor in the conduct of the trial, will occur. Unless required by law, only your doctor, the study team, the Sponsor and its authorised representatives, the Therapeutic Goods Administration (TGA), health authorities from other countries where the study drug may be considered for approval (or already approved) and the Bellberry Human Research Ethics Committee will have access to data which identifies you by name or from which your identity is otherwise apparent or can be reasonably ascertained.

All personal information will be used only for the purpose of administering your participation in this study and in accordance with the laws governing the protection and privacy of personal information under Australian privacy legislation. Participants should note that, some data derived from your participation in this study will be sent overseas; the regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. If you have any questions about this direct them to the Principal Investigator.

By signing the attached consent form, you authorise the release of/or access to this confidential information to the relevant study personnel and regulatory authorities as noted above.

In most cases, you have the right to access personal information collected from you in connection with the study and request corrections of any such personal information that is incorrect.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

How long will this permission last?

This authorization will remain in effect until revoked. There is no expiration date. However, you can change your mind and withdraw your permission at any time.

May I withdraw or revoke (cancel) my permission?

You can change your mind at any time and withdraw your permission to allow your health information to be used in the study.

To withdraw or revoke your permission to use your information as part of this study, you can complete the Study Withdrawal Form and inform you Doctor and Care Team.

If you withdraw your permission, you will not be able to continue being in this study or future research related to it. When you withdraw your permission, no new health information, which might identify you, will be gathered after the effective date of your withdrawal or revocation. However, information that has already been gathered may still be used and given to others.

HREC and Governance, Complaints

If you have any further questions regarding this study, please do not hesitate to contact Dr Camdon Fary on 03 9928 6161 .

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Limited on 08 8361 3222.

Participant Consent Form

TITLE:	mymobility™ Clinical Study: A Prospective Multicenter Longitudinal Cohort Study of the mymobility Platform
PROTOCOL NO.:	CLU2018-13CH
SPONSOR:	Accelero Health Partners, LLC (A Zimmer Biomet Company)
LOCATION:	Epworth HealthCare
INVESTIGATOR:	Dr Camdon Fary

I _____the undersigned hereby voluntarily consent to my involvement in the research project titled mymobility™ Clinical Study: A Prospective Multicenter Longitudinal Cohort Study of the mymobility Platform

_____

I acknowledge that the nature, purpose and risks of the research project and alternatives to participation have been fully explained to my satisfaction by Dr _____.

Specifically, the details of the procedure(s) proposed and the anticipated length of time it will take, the frequency with which the procedure(s) will be performed and an indication of any discomfort that may be expected have been explained to me.

- I freely agree to participate in this research project according to the conditions in the Participant Information Sheet which I confirm has been provided to me.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I have been given the opportunity to have a member of my family or another person present while the study is explained to me.
- I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.
- I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event and I consent to this access.
- I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I am 18 years of age or over.
- I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.
- I declare that all my questions have been answered to my satisfaction.
- I have read, or have had read to me, and I understand the Participant Information Sheet, version 1, dated 21st November 2019

Name of Study Participant:

Signature of Study Participant: Date

Declaration by Principal Investigator (PI) or Co-Investigator (CI):

A verbal explanation of the research project, its procedures and risks has been given to the participant and I believe that the participant has understood that explanation.

Signature of person obtaining consent/authorization Date