Supplement 1: Case Report Form

Protocol Title:	Full Title: Lower limb biomechanical characteristics of patients with neuropathic foot ulcers (DFU study) Short title: Diabetes and Foot Ulceration Study
Participant Initials:	
Unique identification number	D F U
Date of Birth:	
Site:	The Townsville Hospital- Diabetes Clinic, Department of Endocrinology & James Cook University Movement Analysis Laboratory
Scheduled date of first Gait analysis investigation	
Participant Alerts: (Allergies or specific requirements)	
Date Completed:	





Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

Case Report Form (CRF) Completion Instructions

Please ensure the headers are completed on each page

- Participant Initials should be recorded as a three-letter sequence of the participant's initials (First, Middle, Last). If the participant does not have a middle name use a dash (-)
- Patient identification-number for the study.

Complete all pages in a medium to heavy point black ink pen ONLY

Ensure all figures are written inside the designated space, try not to touch the boundaries of this space to maximise accuracy

All text and explanatory comments should be brief and written within the space provided

To answer multiple choice questions place a cross (X) inside the designated space

DO NOT use liquid paper or permanently remove or cover an error. To make a correction, drawn a single line through the original value and write the new value as close as possible to the original space. Initial and date the correction

Do not fold the forms.

If there are any questions please contact the principal study investigator:

Mr. Malindu (Mal) Fernando
Podiatrist and Cohort Doctoral Candidate

James Cook University, Faculty of Medicine and Molecular Sciences.

Telephone: +61 7 47813144

Fax: + 61 7 47813179

Email- malindu.fernando@my.jcu.edu.au

	Diabetes and Foot ulceration Study					
Uniq Num	ue Identification ber:	UR:	Name:			
DOB	:	Initials:				
Incl	gibility Criteria usion Criteria	1	, Part 1- Site The Town			
	ible	now must be unswere	a 120 joi the participant to	be considered		
1		oant been clinically di us or receiving medic	•	☐ Yes ☐ No		
2	Is the participar	nt able to walk unass	sted, utilising two feet?	☐ Yes ☐ No		
3	Has the particip	pant agreed to compl ^e I instructions?	y with all study	☐ Yes ☐ No		
All	ible	elow must be answere	ed NO for the participant to petes	be considered Yes No		
2	Is the participant an amoutee, either BKA or have any foot					
3	Does the participant have a known vascular reconstruction or					
4	Has the particip	oant previously had fo	oot and ankle surgery?	☐ Yes ☐ No		
5	Does the partic	ipant have a bleeding	g disorder?	☐ Yes ☐ No		
6	Is the participar	nt under 18 years of a	nge?	☐ Yes ☐ No		
7	Does the partic	ipant require ambula	tory assistance?	☐ Yes ☐ No		
8	Is the participa	nt pregnant?		☐ Yes ☐ No		
all	Note- If the patient has a present plantar foot ulcer, allocate patient to case group and if not, allocate patient to control group.					

Page 3 of **51**

No

Yes

Is the participant a healthy control?

		Diabetes and Foo	t ulceration Stud	dy	
Unique Identification Number:	UR:		Name:		
DOB:	Initials	s:			
Visit 1					
Informed Consent					
PICF version		Pat	ient Has conse A E		tions
Date on which Inform (dd/mm/yyyy)	ned Co	onsent was obta		/ 🗆 🗆 🖸	
<u>Demographics</u>					
Date of birth \Box \Box /			(dd/mm/yyyy)		
Gender				Male	☐ Female
Caucasian Asian African Aboriginal/ Torres st Other		anicity ander			
Aboriginal or Torres strait Islander? Yes No					
Smoking status Never smoked Ex-smoker (has not month)* *If an ex- or current shows the same states of the	smoke oking	er please answer	Current smok the following	er*	
Average number of o	igaret	tes per day 🗀 🛚			
Medical History Please note that the or treatment	defini	tion of these cor	nditions is base	d on a histo	
Hypertension			☐ Yes ☐ No		
Dyslipidemia			Yes No		
Stroke/ TIA – Date			☐ Yes ☐ No		
Peripheral Arterial Disease			☐ Yes ☐ No		
Cancer or other neoplastic syndrome			☐ Yes ☐ No		
Ischemic Heart Disea	ise				☐ Yes ☐ No
Cardiac or vascular surgery-				☐ Yes ☐ No	

	Diabetes and Foo	ot ulceration Study	
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		
Congestive Heart Fai	lure		Yes No
Chronic Pulmonary [Yes No
Chronic Liver Disease	2		☐ Yes ☐ No
Chronic Renal Impair	ment		☐ Yes ☐ No
DVT- Deep vein thro	mbosis		Yes No
Charcot's neuroarth	ropathy/ Charcot foot		Yes No
Visual impairment fr	om Macular degenera	ation or Glaucoma/ other	Yes No
Diahotos and ulcor	history		
Diabetes and ulcer l Year and month Diag		Uses insulin as a part of o	diahetes
Duration	years and	management? Yes No	madetes
Positive Family Histo		HAB1C-	
Have you had a foot Yes No	ulcer in the past?	Has this ulcer been plant Yes No	ar in location?
Is the present ulcer i where you had the la Yes No		Have you had more than ulcer in the past? Yes No	one previous
	urs a week would you work, home, leisure)	How many hours a your feet and walk	•
3. Do you do reg includes walkii Yes No	hrshrsular exercise that ng?	4. Do you get pain in buttock areas that walking regularly? Yes No	•
3A. If yes how many walking is this?		5. How many hours a your feet (resting, s	sleeping, sitting
	hrs.		hrs.
	Total hours in three n 	nonths standing (weight be hrs	earing)

Diabetes and foot diceration study CKF – Version 26/04/2015

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

Medication	<u>Use</u>	Daily Dose

Footwear Assessment

What type of shoe do you currently use most of the time?

1. Sports 2. Dress 3. Diabetic special shoe 4. Custom made shoe 5. Thongs 6. None

On average per week how many days do you use this shoe?

Days out of seven?

/7

Do you wear orthoses? Yes No

Custom Off-the shelf

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

Physical Measurements

Height: 🗆 🗆 cm	Weight: 🗌 🗎 🗎 kg
BMI:	
Waist circumference cm	
Hip circumferencecm	

Visual test (Diabetic retinopathy)

Has the patient seen an optometrist in the last 12 months? Yes No Optometrist Details-

Does the patient need optometrist referral?

Visual acuity score-

Podiatric Examination- To be conducted using a goniometer for values for ROM

Examination	Right			Left		
Ankle Joint ROM (deg)						
STJ ROM (deg)						
1 st MTPJ ROM (deg)						
HAV- Hallux Abducto Valgus						
Deformity Stage Manchester						
Scale						
Foot type	Pes Planu	S		Pes Pl	anus	
	Pes Cavus			Pes Ca	ivus	
	Regular A	rch Con	tour	Regula	ar Arch Conto	ur
Muscle strength DF/PF	1	2	3	1	2	3
	4	5		4	5	
Muscle Strength Inv/Evr	1	2	3	1	2	3
	4	5		4	5	
Muscle Strength Abduction/	1	2	3	1	2	3
Adduction	4	5		4	5	

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

Lesser toe deformities (Claw	Claw Toe			Claw T	oe		
toe, Hammer Toe, Mallet toe)	Hammer Toe			Hammer Toe			
	Mallet To	e		Mallet	Toe		
Plantar hyperkeratosis	Plantar fir	st meta	tarsal head	Planta	r first metata	arsal head	
locations	Plantar Pl	MA 1-3		Planta	r PMA 1-3		
	Plantar A	oex of to	es	Planta	r Apex of toe	es .	
	Plantar Ca	alcaneal	area	Planta	r Calcaneal a	rea	
	Medial Ha	allux		Medial Hallux			
	Plantar 5 ^t	Plantar 5 th metatarsal head			Plantar 5 th metatarsal head		
	Plantar PMA 4-5			Plantar PMA 4-5			
	Plantar Cuboid			Planta	r Cuboid		
Lunge test	<35 Degre	ees		<35 De	egrees		
	35 Degree	es		35 Degrees			
	>35 Degre	ees		>35 De	egrees		
MSRT	1	2	3	1	2	3	
	4	5		4	5		
Jack's test	Positive	•		Positiv	е		
	Negative			Negati	ve		

Vascular and Neurological examination

vascular and ivediblogical examination			
Investigation	Right	Left	
Foot Pulses			
Posterior Tibialis	Present/Normal Reduced Absent	Present/Normal Reduced Absent	
Dorsalis Pedis	Present/Normal Reduced Absent	Present/Normal Reduced Absent	
Anterior tibialis	Present/Normal Reduced Absent	Present/Normal Reduced Absent	
ABI			
Brachial	1	1	
Posterior Tibialis	2	2	
Dorsalis Pedis	3	3	
Anterior Tibial	4	4	
	ABI =	ABI =	
Toe perfusion pressure	1	1	
(Hallux Pressure)	2	2	
	3	3	
	Mean=	Mean=	
Monofilament test	 Plantar Hallux 	1. Plantar Hallux	
Site specification (/10)	2. Plantar metatarsal 2	2. Plantar metatarsal 2	
	3. Plantar metatarsal 3	3. Plantar metatarsal 3	
	4. Plantar metatarsal 4	4. Plantar metatarsal 4	
	5. Plantar metatarsal 5	5. Plantar metatarsal 5	
	6. Plantar Arch- (Navicular)	6. Plantar Arch- (Navicular)	
	7. Plantar 2 nd toe apex	7. Plantar 2 nd toe apex	

Diabetes and Foot ulceration Study		
Unique Identification Number:	UR:	Name:
DOB:	Initials:	

	8. Plantar 5 th toe apex	8. Plantar 5 th toe apex
	9. Dorsal Hallux	9. Dorsal Hallux
	10. Plantar Medial Tubercle	10. Plantar Medial Tubercle
Neurothesiometer Reading at	>25 V	>25 V
which vibration felt at tip of	25 V	25 V
hallux.	< 25 V	< 25 V

Does the patient have a present plantar foot ulcer?

Yes No

Planimetry and Ulcer assessment

Investigation	Ulcer 1	Ulcer 2	Ulcer 3
Ulcer Location			
Estimated duration of			
ulcer			
In weeks			
Planimetric depth			
cm3			
Planimetry			
Length cm	Lengthcm	Lengthcm	Lengthcm
Width cm	Widthcm	Widthcm	Widthcm
Area cm	Areacm	Areacm	Areacm
Wound exudate/	Mild Serous	Mild Serous	Mild
discharge present	Moderate	Moderate Purulent	Serous
and type of exudate	Purulent	High	Moderate
	High	Haemoserous	Purulent
	Haemoserous		High
			Haemoserous
UTWCS Grading			
Wound Bed	Necrotic	Necrotic	Necrotic
	Granulating	Granulating	Granulating
	Epithelializing	Epithelializing	Epithelializing
	Sloughy	Sloughy	Sloughy
	Pale	Pale	Pale

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

	Hypergranulating	Hypergranulating	Hypergranulating
Marrad Edge	Bone	Bone	Bone
Wound Edge	Regular	Regular	Regular
	Irregular	Irregular	Irregular
	Undermined	Undermined	Undermined
	Rolling	Rolling	Rolling
Sinus Formation	Yes No	Yes No	Yes No
Yes No	mm	mm	_
Is the ulcer infected?	Yes	Yes	Yes
-Conduct Wound			
Swab for presence of	No	No	No
pathological			
microbes.			
Type of organism			
causing infection (As			
per pathology test)			
Type of ulcer	Neuropathic	Neuropathic	Neuropathic
(Neuropathic,			
Neuroischemic)	Neuroischemic	Neuroischemic	Neuroischemic
Surrounding Skin	Macerated	Macerated	Macerated
	Hyperkeratotic	Hyperkeratotic	Hyperkeratotic
	Indurated	Indurated	Indurated
	Normal/healthy	Normal/healthy	Normal/healthy
	Fragile	Fragile	Fragile
	Erythematous	Erythematous	Erythematous
	Oedematous	Oedematous	Oedematous
	Anhidrotic	Anhidrotic	Anhidrotic
Orthoses Used?	Yes No	Yes No	Yes No
Offloading shoe or	Yes No	Yes No	Yes No
boot-walker used?			
Type of Off-loading	TCC	TCC	TCC
Device	Foot Orthoses	Foot Orthoses	Foot Orthoses
	AFO	AFO	AFO
	Padding	Padding	Padding
	No offloading	No offloading	No offloading
How often is the			
ulcer seen by a health			
professional in a			
month? (X 3)			
` '			

Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			
How often is the ulcer dressing changed per month? (x 3)				

Is a photograph of the ulcer taken?

Yes No

Note

Quality of life questionnaire to be handed to the patient at this point to fill out then the details and dates for gait assessment visit and follow-up visit on a follow-up card should be given to the patient. Contact details are then recorded separately.

Pedometer Given to Patient? Yes No

Blood Collection – Pathology

Refer patient to SNP pathology for blood collection.

Blood collection form given to patient?	□ Yes □ No
Date of Collection	/(dd/mm/yyyy)
Haemoglobin □□□g/L	LD □□□U/L
WCC □□.□10 ⁹ /L	Cholesterol □.□mmol/L
Platelets □□□10 ⁹ /L	Triglyceride □.□mmol/L
Fibrinogen □.□□g/L	HDL □.□mmol/L
Sodium □□□ mmol/L	LDL □.□mmol/L
Potassium □.□ mmol/L	CRP 🗆 🗆 mg/L
Urea □□□ mmol/L	Chloride mmol/L
Creatinine □□□ µmol/L	Bicarbonate □□mmol/L

	Diabetes and Foo	t ulceration Study
Unique Identification Number:	UR:	Name:
DOB:	Initials:	
eGFR 🗆 🗆 mL/min/1.7	73m²	Calcium □.□□mmol/L
Fasting Glucose	μmol/L	Phosphorus □.□mmol/L
HbA1C	%	Total protein □□g/L
CRPmg/l	L	Hematocrit □.□□mg/dL
ESRmm/hr		Neuts □.□10 ⁹ /L
Parathyroid Hormonepg/ml		Lymphs □.□10 ⁹ /L
N-(carboxymethyl) lysine (CML)		Monos □.□10 ⁹ /L
Non-CML advanced glycation end products (AGEs)		Eos □.□10 ⁹ /L
Pentosidine		Baso □.□□10 ⁹ /L
Homocystine		

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		
Vascular Biolo		od Sample Storage Form Staff to complete	
Has blood been colle		_	
analysis? (Check with	•	Yes No	
Date of Collection		(dd/mm/yyyy)	
2 x SST		☐ Yes ☐ No	
2 x EDTA		☐ Yes ☐ No	
1 x Sodium Citrate		☐ Yes ☐ No	
Sample Storage			
Have study bloods been processed and stored according to the lab manual?		Yes No* *If NO, record a Protocol Deviation	
Date of Processing			
	Number of Samples:	Have samples been stored at the Protocol defined temperature? Location of Samples	
Serum (from SST tubes)	(Store at -80°C)	Yes No* *If NO, record a Protocol Deviation *If NO, record a Protocol Deviation	
EDTA Plasma (Purple top EDTA tubes)	(Store at -80°C)	Yes No* *If NO, record a Protocol Deviation *If NO, record a Protocol Deviation	
EDTA RBC Pellet (Remaining pellet from El tubes with plasma remov	i isibie at	Yes No* *If NO, record a Protocol Deviation *If NO, record a Protocol Deviation	
Citrate Plasma (Blue top Citrate tubes)	(Store at -80°C)	Yes No* *If NO, record a Protocol Deviation *If NO, record a Protocol Deviation	

Unique Identification			
Number:	UR:	Name:	
DOB:	Initials:		
Patient has comple	eted blood test		☐ Yes ☐ No
Patient fulfils the c	riteria for the study?		☐ Yes ☐ No
Patient is going to I	be placed in the grou	p	Case
Dationt has filled a		action naive /a	Control
Patient has filled of	ut a quality of life que	estionnaire/s	☐ Yes ☐ No
Patient has been a and location of the	=	assessment date and time	☐ Yes ☐ No
Patient has been a	dvised of the date of	next visit and advised to	Yes No
come after fasting	for this, as if having a	blood test	
Name Unique Identificati	ion Number -		
Telephone number	r		
. C.CpCCC.			
Address			
-			
Address	ate and time -		
Address Email Gait Assessment d	ate and time - sit date (3 months) -		
Address Email Gait Assessment d			
Address Email Gait Assessment d Next estimated vis	it date (3 months) -	ncing Gait assessm	nent
Address Email Gait Assessment d Next estimated vis	it date (3 months) -		nent_
Address Email Gait Assessment d Next estimated vis Pr Claudication Quest	it date (3 months) -	es† No	<u>ient</u>
Address Email Gait Assessment d Next estimated vis Pr Claudication Quest	it date (3 months) - ior to Comme ionnaire Checked? Ye al range for participat	es† No	nent_

Notes:

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

<u>Visit 1 – Part 2: Gait, Pressure and Biomechanical</u> <u>Assessment.</u>

Site- James	s Cook Un	iversity, Gai	it Laborato	ry.
Physical Measurements		-		_ _
ASIS Breadth	cm	Mass:	□□kg	
Left Leg length	cm	Height	cm	
Left Knee diameter	cm			
Left malleolus width	cm			
Right Leg length	cm			
Right Knee diameter	cm			
Right malleolus width	cm			
Testing protocol				
Measure up:				
-				_
EMG prep:				
MVC:				
Reflective markers prep				
Static capture				
10 walking trails				
Treadmill walking 4 minu	tes			
(Capture only 2:00 onwar Self-Selected Walking Spe	*		km/hr.	
Plantar pressure capture (3	3 walks)			

FINISHED

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

Data-Sets Post-Data extraction

Primary	Measurement	Left	<u>Right</u>
<u>Outcome</u>			
<u>measure</u>			
Peak plantar	Medial Heel-		
pressure	Lateral Heel		
(N/Cm2)	Medial Forefoot		
	Lateral Forefoot		
Pressure time	Medial Heel-		
integral	Lateral Heel		
(N/Cm2) X s	Medial Forefoot		
	Lateral Forefoot		
Time of peak	Vastus Lateralis		
occurrence	Lat		
EMG (%)	Gastrocnemius		
	Tibialis Anterior		
GRF	Vertical		
(N/Kg)^D	Med/Lat		
	Ant/Post		
Oxford Foot	Hindfoot Sag		
Model	Hindfoot Fron		
(deg)	Hindfoot T.V		
	Forefoot Sag		
	Forefoot Fron		
	Forefoot T.V		
Lower Limb	Stance Phase		
Kinematics	Max hip Flex		
	Max hip Ext		
	Max Knee Flex		
	Max Knee Ext		
	Max Ankle DF		
	Max Ankle PF		
	Curing Dhace		
	Swing Phase		
	Max hip Flex		
	Max hip Ext Max Knee Flex		
	Max Knee Flex		
	Max Ankle DF		
	Max Ankle PF		
	I I I I I I I I I I I I I I I I I I I		

EMG During Gait Assessment

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

Maximum Voluntary Contraction

<u>Tibialis</u>	Medial Gastroc	Lateral	<u>Peroneus</u>	Soleus	<u>VMO</u>	<u>Semiten</u>
<u>Anterior</u>		<u>Gastroc</u>	<u>Longus</u>			
Right						
<u>Left</u>						

<u>(%)</u>	<u>Tibialis</u> Anterior	<u>Medial</u> Gastroc	<u>Lateral</u> Gastroc	Peroneus Longus	Soleus	<u>VMO</u>	<u>Semiten</u>
<u>Peak</u>							
Activation							
Left							
Right							
<u>Contact</u>							
Left							
Right							
<u>Stance</u>							
Left							
Right							
Toe-off							
Left							
Right							
<u>Swing</u>							
Left							
Right							

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

Treadmill gait assessment

	<u> 113</u>	eaumm yan assessment	
Assessment	Parameter	Left	Right
Oxford Foot	Hindfoot Sag		
Model	Hindfoot Fron		
(deg)	Hindfoot T.V		
	Forefoot Sag		
	Forefoot Fron		
	Forefoot T.V		
Lower Limb	Stance Phase		
Kinematics	Max hip Flex		
	Max hip Ext		
	Max Knee Flex		
	Max Knee Ext		
	Max Ankle DF		
	Max Ankle PF		
	Swing Phase		
	Max hip Flex		
	Max hip Ext		
	Max Knee Flex		
	Max Knee Ext		
	Max Ankle DF		
	Max Ankle PF		

EMG During Treadmill Gait

Muscle	<u>Tibialis</u>	Medial	Lateral	Peroneus	Soleus	<u>VMO</u>	<u>Semitendinosus</u>
	<u>Anterior</u>	<u>Gastroc</u>	<u>Gastroc</u>	<u>Longus</u>			
<u>Peak</u>							
<u>Activation</u>							
Left							
Right							
MVC							
Left							
Right							
Contact							
Left							
Right							
<u>Stance</u>							
Left							

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

Right				
Toe-off Left Right Swing Left Right				
<u>Swing</u> Left Right				

- 1. Blood Collection Form Given
- 2. Questionnaires Collected (4)
- 3. Review-date organised
- 4. Pedometer calibrated and given?
- 5. Instructions given on Pedometer return?

Notes

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

<u>Visit 2</u> <u>At 3 Months –Townsville hospital Diabetes clinic</u>

<u>initiai</u>	<u>assessment</u>	
1	Is the participant in the case or control group?	Case
		Control
2	Does the participant have a present plantar foot ulcer?	Yes 🗌 No
3	Does the participant have a newly formed plantar ulcer?	Yes 🗌 No
3A	Has a plantar ulcer healed in this duration?	Yes No
4	Does the participant give consent for biopsy of the ulcer/ulcers?	☐ Yes ☐ No
5	Has the participant's diabetes medication or dose changed since last visit? Please note changes: 1. 2. 3. 4. 5.	☐ Yes ☐ No
6	Has the participant increased/decreased treatment frequency for the ulcer?	☐ Yes ☐ No
	If yes, how so?	Increased
		Decreased
7	Has the patient commenced any new treatment for a disease process or as a part of a health measure? I.e Dialysis, HRT, Warfarin treatment, Radiation therapy	☐ Yes ☐ No
	Please state	
8	Has the patient commenced or is awaiting any surgical procedure?	☐Yes ☐ No
	Please state	
9	Has the patient increased or decreased weight-bearing activity levels in the last 3 months?	☐Yes ☐ No
	Please state new number of hours per week, on weight-bearing activities?hrs	

Diabetes and Foot ulceration Study					
Unique Identification Number:		UR:	Name:		
DOB:		Initials:			
	Please state t	urs per week weight- i.e. standing)			
	Please state t bearing (Sitti	<u>.</u>	ompletely not weight		
Total	Total hours in	n three months standii			
		hrs	(e. g		
	Total hours in	g (weight bearing)			
	Total hours in	n three months non-w	eight bearing hrs		

Physical Measurements

Weight: 🗌 🗎 🗎 kg	Waist circumferencecm
BMI:	Hip circumferencecm

Podiatric Examination- To be conducted using a goniometer for values for ROM

Examination	Right			Left		
Ankle Joint ROM (deg)						
STJ ROM (deg)						
1 st MTPJ ROM (deg)						
HAV- Hallux Abducto Valgus						
Deformity Stage Manchester						
Scale						
Foot type	Pes Plan	nus		Pes Pla	nus	
	Pes Cavi	us		Pes Ca	vus	
	Regular	Arch Conto	our	Regula	r Arch Conto	our
Muscle strength DF/PF	1	2	3	1	2	3
	4	5		4	5	
Muscle Strength Inv/Evr	1	2	3	1	2	3
	4	5		4	5	
Muscle Strength Abduction/	1	2	3	1	2	3
Adduction	4	5		4	5	

Diabetes and Foot ulceration Study						
Unique Identification Number:	UR:	Name:				
DOB:	Initials:					

Lesser toe deformities (Claw	Claw Toe	Claw Toe			е	
toe, Hammer Toe, Mallet toe)	Hammer Toe			Hammei	r Toe	
	Mallet Toe			Mallet T		
Plantar hyperkeratosis	Plantar first metatarsal head			Plantar first metatarsal head		
locations	Plantar PM	A 1-3		Plantar I	PMA 1-3	
	Plantar Ape	ex of toes	5	Plantar A	Apex of to	es
	Plantar Cal	caneal ar	ea	Plantar (Calcaneal a	area
	Medial Hall	ux		Medial F	Hallux	
	Plantar 5 th	metatars	al head	Plantar 5 th metatarsal head		
	Plantar PM	A 4-5		Plantar PMA 4-5		
	Plantar Cub	oid		Plantar Cuboid		
Lunge test	<35 Degree	es		<35 Degrees		
	35 Degrees			35 Degre	ees	
	>35 Degree	es		>35 Deg	rees	
MSRT	1	2	3	1	2	3
	4	5		4	5	
Jack's test	Positive			Positive		
	Negative			Negative	9	

Does the patient have a present plantar foot ulcer? Yes No

If yes, please fill out planimetry and ulcer assessment table below.

Planimetry and Ulcer assessment

Investigation	Ulcer 1		Ulcer 2		Ulcer 3	
Ulcer Location						
Estimated duration of						
ulcer						
In weeks						
Planimetric depth						
cm3						
Planimetry						
Length cm	Length	cm	Length	cm	Length	cm
Width cm	Width	cm	Width	cm	Width	cm
Area cm	Area	_cm	Area	_cm	Area	_cm
Wound exudate/	Mild	Serous	Mild	Serous	Mild	
discharge present	Moderate		Moderate	Purulent	Serous	
and type of exudate	Purulent		High		Moderate	

Diabetes and Foot ulceration Study						
Unique Identification Number:	UR:	Name:				
DOB:	Initials:					

	High Haemoserous	Haemoserous	Purulent High Haemoserous
UTWCS Grading			
Wound Bed	Necrotic Granulating Epithelializing Sloughy Pale Hypergranulating Bone	Necrotic Granulating Epithelializing Sloughy Pale Hypergranulating Bone	Necrotic Granulating Epithelializing Sloughy Pale Hypergranulating Bone
Wound Edge	Regular Irregular Undermined Rolling	Regular Irregular Undermined Rolling	Regular Irregular Undermined Rolling
Sinus Formation Yes No	Yes No mm	Yes No	Yes No mm
Is the ulcer infected? -Conduct Wound Swab for presence of pathological	Yes No	Yes No	Yes
microbes. Type of organism causing infection (As per pathology test)			
Type of ulcer (Neuropathic,	Neuropathic	Neuropathic	Neuropathic
Neuroischemic)	Neuroischemic	Neuroischemic	Neuroischemic
Surrounding Skin	Macerated Hyperkeratotic Indurated Normal/healthy Fragile Erythematous Oedematous Anhidrotic	Macerated Hyperkeratotic Indurated Normal/healthy Fragile Erythematous Oedematous Anhidrotic	Macerated Hyperkeratotic Indurated Normal/healthy Fragile Erythematous Oedematous Anhidrotic
Orthoses Used? Offloading shoe or boot-walker used?	Yes No Yes No	Yes No Yes No	Yes No Yes No

	Diabetes and Foo	t ulceration Study	
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		
Type of Off-loading Device	TCC Foot Orthoses AFO Padding No offloading	TCC Foot Orthoses AFO Padding No offloading	TCC Foot Orthose AFO Padding No offloading
How often is the ulcer seen by a healt professional in a month? (X 3)	h		
How often is the ulcer dressing changed per month? (x 3)			
_	oh of the ulcer	taken?	Yes No
What type of shoe do 1. Sports 2. Dress 6.None	Footwear and you currently use made as a second sec	Assessment ost of the time? oe 4.Custom made shoe	5.Thongs
What type of shoe do 1. Sports 2. Dress 6.None On average per week Days out of seven? Do you wear orthose	Footwear and you currently use many days do you many days do you want with the control of the co	Assessment ost of the time? oe 4.Custom made shoe ou use this shoe? Custom Off-the	e 5.Thongs e shelf
What type of shoe do 1. Sports 2. Dress 6.None On average per week Days out of seven? Do you wear orthose	Footwear and you currently use many days do you many days	Assessment ost of the time? oe 4.Custom made shoe ou use this shoe? Custom Off-the	e 5.Thongs e shelf
What type of shoe do 1. Sports 2. Dress 6.None On average per week Days out of seven? Do you wear orthose Blood Collection – Pa	Footwear and you currently use many days do you many days	Assessment ost of the time? oe 4.Custom made shoe ou use this shoe? Custom Off-the	e 5.Thongs e shelf
Uhat type of shoe do 1. Sports 2. Dress 6.None On average per week Days out of seven? Do you wear orthose Blood Collection – Pa	Footwear or you currently use many days do you for many days do you for many for many days do you for many days do you for many for many days do you for many for man	Assessment ost of the time? oe 4.Custom made shoe ou use this shoe? Custom Off-the	e 5.Thongs e shelf
What type of shoe do 1. Sports 2. Dress 6.None On average per week Days out of seven? Do you wear orthose Blood Collection — Pa	Footwear or you currently use many days do you for many days do you for many for many days do you for many days do you for many for many days do you for many for man	Assessment ost of the time? oe 4.Custom made shoe ou use this shoe? Custom Off-the ology for blood collection Yes (d	e 5.Thongs e shelf

 $HDL \square. \square mmol/L$

LDL □.□mmol/L

Fibrinogen □.□□g/L

Sodium □□□ mmol/L

	Diabetes and Foo	t ulceration Study
Unique Identification Number:	UR:	Name:
DOB:	Initials:	
Potassium □.□ mmol/	L	CRP □□□mg/L
Urea □□□ mmol/L		Chloride □□□mmol/L
Creatinine □□□ µmol,	/L	Bicarbonate □□mmol/L
eGFR 🗆 🗆 mL/min/1.7	73m²	Calcium □.□□mmol/L
Fasting Glucose □□.□	μmol/L	Phosphorus □.□mmol/L
HAB1C	%	Total protein □□g/L
CRPmg/	L	Hematocrit □.□□mg/dL
ESRmm	n/hr	Neuts □.□10 ⁹ /L
Parathyroid Hormone	pg/ml	Lymphs □.□10 ⁹ /L
N-(carboxymethyl) lys	ine (CML)	Monos □.□10 ⁹ /L
Non-CML advanced glv (AGEs)	ycation end products	Eos □.□10 ⁹ /L
Pentosidine		Baso □.□□10 ⁹ /L
Homocystine		

Note

Quality of life questionnaire to be handed to the patient at this point to fill out then the details and dates for gait assessment visit and follow-up visit on a follow-up card should be given to the patient. Contact details are then recorded separately.

Pedometer Given to Patient? Yes No

		Diabetes and	Foo	t ulceration Study		
Unique Identification Number:	UR:			Name:		
DOB:	Initial	ls:				
Vascular Rio	logy	Unit Blog	<u> </u>	Sample Storage Fo	rm	
vasculai bio	iogy	OHIL BIOL	<u>)u</u>	Sample Storage Fo	<u></u>	
Blood Collection –F	or VBl	J Biomarker S	Staf	ff to complete		
Has blood been coll analysis? (Check wi		•)	☐ Yes ☐	No	
Date of Collection				(dd/mm/yyyy)		
2 x SST					No	
2 x EDTA				☐ Yes ☐ No		
1 x Sodium Citrate				☐ Yes ☐ No		
Sample Storage						
Have study bloods	been p	rocessed		☐ Yes ☐ No	*	
and stored according manual?	ng to th	ne lab		*If NO, record a Protocol De		
Date of Processing					(dd/mm/yyyy)	
		Number of Samples:	Н	ave samples been stored at the Protocol defined temperature?	Location of Samples	
Serum (from SST tubes)		(Store at -80°C)	*	Yes No* f NO, record a Protocol Deviation	Box # Position #	
EDTA Plasma (Purple top EDTA tubes	:)	(Store at -80°C)	*	Yes No* f NO, record a Protocol Deviation	Box # Position #	
EDTA RBC Pellet (Remaining pellet from tubes with plasma remo		(Store at -80°C)	*	Yes No* f NO, record a Protocol Deviation	Box # Position #	
					Box#	

Notes:

Citrate Plasma

(Blue top Citrate tubes)

Position #

*If NO, record a Protocol Deviation

(Store at -80°C)

Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

Biopsy Procedure Documentation Sheet-Foot ulcer patients Only!

Has informed consent been obtained for biopsy? Yes No

Have VBU staff been advised about time of biopsy collection? Yes No

Appropriate transport medium organised? Yes No

Doctors Statement

I have explained

- The patient's condition
- Need for the biopsy
- The procedure and the risk
- Relevant treatment options and their risks
- Likely consequences if those risks occur
- The significant risks and problems specific to this patient.

I have given the patient/substitute decision maker an opportunity to

- Ask questions about any of the above matters
- Raise any other concerns

Which I have answered as fully as possible. I am of the opinion that the patient/substitute decision maker understands the above information.

Name of Doctor	
Designation	
Date	_
Signature	

Biopsy Sample appropriately stored at the VBU? Yes No

Date of storage of Sample-

Part 2: Gait, Pressure and Biomechanical Assessment.

		l Foot ulceration Stu	dy	
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			
Site- J	ames Cook U	niversity. Gai	t Laborat	orv.
		inversity, car	<u>C Edbord</u>	<u> y .</u>
Physical Measuren ASIS Breadth	cm	Mass:	 kg	
Left Leg length	cm	Height	cm	
Left Knee diameter	r cm			
Left malleolus widt	:h cm			
Right Leg length	cm			
Right Knee diameto	er cm			
Right malleolus wid	dth cm			
Testing protocol				
Measure up:				ш
EMG prep:				
MVC:				
Reflective markers	prep			
Static capture				
10 walking trails				
Treadmill walking	4 minutes			
(Capture only 2:00 Self-Selected Walk			km/hr.	
Plantar pressure ca	pture (3 walks)			

FINISHED

Diabetes and Foot ulceration Study					
Unique Identification Number:	UR:	Name:			
DOB:	Initials:				

Primary Outcome	<u>Measurement</u>	<u>Left</u>	Right
<u>measure</u>			
Peak plantar	Medial Heel-		
pressure	Lateral Heel		
(N/Cm2)	Medial Forefoot		
	Lateral Forefoot		
Pressure time	Medial Heel-		
integral	Lateral Heel		
(N/Cm2) X s	Medial Forefoot		
	Lateral Forefoot		
Time of peak	Vastus Lateralis		
occurrence	Lat		
EMG (%)	Gastrocnemius		
	Tibialis Anterior		
GRF	Vertical		
(N/Kg)^D	Med/Lat		
	Ant/Post		
Oxford Foot	Hindfoot Sag		
Model	Hindfoot Fron		
(deg)	Hindfoot T.V		
	Forefoot Sag		
	Forefoot Fron		
Lauran Linala	Forefoot T.V		
Lower Limb	Stance Phase		
Kinematics	Max hip Flex		
	Max hip Ext Max Knee Flex		
	Max Knee Ext Max Ankle DF		
	Max Ankle PF		
	Max Alikie Pr		
	Swing Phase		
	Max hip Flex		
	Max hip Ext		
	Max Knee Flex		
	Max Knee Fiex		
	Max Ankle DF		
	Max Ankle PF		

Data-Sets Post-Data extraction

EMG During Gait Assessment

Diabetes and Foot ulceration Study					
Unique Identification UR: Name: Number:					
DOB:	Initials:				

Maximum Voluntary Contraction

<u>Tibialis</u>	Medial Gastroc		<u>Peroneus</u>	<u>Soleus</u>	<u>VMO</u>	<u>Semiten</u>
Anterior Right		Gastroc	Longus			
l oft						
<u>Left</u>						

(%)	Tibialis Aptorior	<u>Medial</u>	<u>Lateral</u>	Peroneus	Soleus	<u>VMO</u>	<u>Semiten</u>
D 1	<u>Anterior</u>	Gastroc	Gastroc	<u>Longus</u>			
<u>Peak</u>							
<u>Activation</u>							
Left							
Right							
Contact							
Left							
Right							
<u>Stance</u>							
Left							
Right							
Toe-off							
Left							
Right							
<u>Swing</u>							
Left							
Right							

Treadmill gait assessment

Assessment	Parameter	Left	Right

Diabetes and Foot ulceration Study				
Unique Identification	UR:	Name:		
Number:				
DOB:	Initials:			

		<u> </u>	
Oxford Foot Model (deg)	Hindfoot Sag Hindfoot Fron Hindfoot T.V Forefoot Sag Forefoot Fron		
	Forefoot T.V		
Lower Limb Kinematics	Stance Phase Max hip Flex Max hip Ext Max Knee Flex Max Knee Ext Max Ankle DF Max Ankle PF		
	Swing Phase Max hip Flex Max hip Ext Max Knee Flex Max Knee Ext Max Ankle DF Max Ankle PF		

EMG During Treadmill Gait

Muscle	<u>Tibialis</u>	Medial	<u>Lateral</u>	<u>Peroneus</u>	Soleus	<u>VMO</u>	Semitendinosus
	<u>Anterior</u>	<u>Gastroc</u>	<u>Gastroc</u>	<u>Longus</u>			
<u>Peak</u>							
<u>Activation</u>							
Left							
Right							
MVC							
Left							
Right							
Contact							
Left							
Right							
<u>Stance</u>							
Left							
Right							

	Diabetes and Foot ulceration Study							
	Unique Identification Number:	UR:		Name:				
	DOB:	Initials	:					
Toe-off Left Right Swing								
Left Right								

Summary of Findings

Is the initial ulcer still present? Has the ulcer size increased? Has the ulcer size decreased? YES NO Is there formation of a new ulcer? Has the ulcer completely healed? Has the ulcer completely healed? YES NO Is there a decrease in glycaemic control? VES NO Is there a decrease in renal function? Is there a decrease in renal function? Has the patient commenced dialysis? YES NO Is there increased AGE formation PES NO Is there differences in the ROM of Joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Was a biopsy conducted? Was a biopsy conducted? YES NO Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study? Next visit date provided? YES NO			
Has the ulcer size decreased? Is there formation of a new ulcer? Has the ulcer completely healed? Is there a decrease in glycaemic control? Is there a decrease in renal function? Has the patient commenced dialysis? Is there increased AGE formation PYES NO Is there differences in the ROM of joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? YES NO Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Is the initial ulcer still present?	YES	NO
Is there formation of a new ulcer? Has the ulcer completely healed? Is there a decrease in glycaemic control? Is there a decrease in renal function? Has the patient commenced dialysis? Is there increased AGE formation Present? Are there differences in the ROM of joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? YES NO Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Has the ulcer size increased?	YES	NO
Has the ulcer completely healed? Is there a decrease in glycaemic control? Is there a decrease in renal function? Has the patient commenced dialysis? Is there increased AGE formation Present? Are there differences in the ROM of joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Has the ulcer size decreased?	YES	NO
Is there a decrease in glycaemic control? Is there a decrease in renal function? Has the patient commenced dialysis? Is there increased AGE formation present? Are there differences in the ROM of joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? Wes NO Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Is there formation of a new ulcer?	YES	NO
Is there a decrease in renal function? Has the patient commenced dialysis? Is there increased AGE formation present? Are there differences in the ROM of joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? Was haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Has the ulcer completely healed?	YES	NO
Has the patient commenced dialysis? Is there increased AGE formation present? Are there differences in the ROM of joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Is there a decrease in glycaemic control?	YES	NO
Is there increased AGE formation present? Are there differences in the ROM of joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Is there a decrease in renal function?	YES	NO
Are there differences in the ROM of joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Has the patient commenced dialysis?	YES	NO
Joints? Is there deterioration of vascular function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?		YES	NO
function? Is there a deterioration of neurological function? Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?		YES	NO
Has there been a reduction in treatment frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?		YES	NO
frequency? Has there been an increase in treatment frequency? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study? NO YES NO YES NO YES NO YES NO NO NO NO NO NO NO NO NO N		YES	NO
frequency? Was a biopsy conducted? Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study? YES NO YES NO YES NO		YES	NO
Is there infection present? Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study? YES NO YES NO NO		YES	NO
Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study?	Was a biopsy conducted?	YES	NO
critically? I.e Lipid profile, WCC, CRP, ESR Is the participant still suitable for the study? NO	Is there infection present?	YES	NO
study?	critically? I.e Lipid profile, WCC, CRP,	YES	NO
Next visit date provided? YES NO		YES	NO
	Next visit date provided?	YES	NO

If the participant is no longer suitable for the study, please send a letter of thanks for being involved in the study, otherwise provide date and time of next consultation.

Diabetes and Foot ulceration Study					
Unique Identification Number:	UR:	Name:			
DOB:	Initials:				

	_	_	_
Data and	d tima at	f novt con	cultation
ale and	a ume o	f next con	Sullation

- 1. Blood Collection Form Given
- 2. Questionnaires Collected (4)
- 3. Review-date organised
- 4. Pedometer calibrated and given?
- 5. Instructions given on Pedometer return?

Notes

<u>Visit 3</u> At 6 Months

Diabetes and Foot ulceration Study					
Unique Identification Number:	UR:	Name:			
DOB:	Initials:				

1	Is the participant in the case or control group?	Case
		Control
2	Does the participant have a present plantar foot ulcer?	Yes 🗌 No
3	Does the participant have a newly formed plantar ulcer?	Yes 🗌 No
3A	Has a plantar ulcer healed in this duration?	Yes No
4	Does the participant give consent for biopsy of the ulcer/ulcers?	☐ Yes ☐ No
5	Has the participant's diabetes medication or dose changed since last visit? Please note changes: 1. 2.	☐ Yes ☐ No
	3.4.5.	
6	Has the participant increased/decreased treatment frequency for the ulcer?	☐ Yes ☐ No
	If yes, how so?	Increased
		Decreased
7	Has the patient commenced any new treatment for a disease process or as a part of a health measure? I.e Dialysis, HRT, Warfarin treatment, Radiation therapy	☐ Yes ☐ No
	Please state	
8	Has the patient commenced or is awaiting any surgical procedure?	Yes 🗌 No
	Please state	
9	Has the patient increased or decreased weight-bearing activity levels in the last 3 months?	Yes 🗌 No
	Please state new number of hours per week, on weight-bearing activities? hrs Please state the new number of hours per week weight-bearing but not doing any activity (ie standing) hrs	
		j

Diabetes and Foot ulceration Study					
Unique Identification Number:	UR:	Name:			
DOB:	Initials:				

	Please state the number of hours completely not weight					
	bearing (Sitting)					
	hrs					
Total	Total hours in three months standing (weight bearing)					
	hrs					
	Total hours in three months walking (weight bearing)					
	hrs					
	Total hours in three months non-weight bearing					
	hrs					

Physical Measurements

Weight: 🗌 🗎 🗎 kg	Waist circumferencecm		
BMI:	Hip circumferencecm		

Podiatric Examination- To be conducted using a goniometer for values for ROM

Examination	Right			Left			
Ankle Joint ROM (deg)							
STJ ROM (deg)							
1 st MTPJ ROM (deg)							
HAV- Hallux Abducto Valgus							
Deformity Stage Manchester							
Scale							
Foot type	Pes Pla	nus		Pes Pla	Pes Planus		
	Pes Cav	/us		Pes Cavus			
	Regulai	r Arch Conto	our	Regular Arch Contour			
Muscle strength DF/PF	1	2	3	1	2	3	
	4	5		4	5		
Muscle Strength Inv/Evr	1	2	3	1	2	3	
	4	5		4	5		
Muscle Strength Abduction/	1	2	3	1	2	3	
Adduction	4	5		4	5		
Lesser toe deformities (Claw	Claw Toe		Claw Toe				
toe, Hammer Toe, Mallet toe)	Hammer Toe		Hammer Toe				
	Mallet Toe		Mallet Toe				
Plantar hyperkeratosis	Plantar	tar first metatarsal head Plantar first metatarsa			arsal head		
locations	Plantar	PMA 1-3		Planta	r PMA 1-3		

Diabetes and Foot ulceration Study						
Unique Identification Number:	UR:	Name:				
DOB:	Initials:					

	Plantar Apex of toes			Plantar Apex of toes			
	Plantar Calcaneal area			Plantar Calcaneal area			
	Medial Hall	ux		Medial Hallux			
	Plantar 5 th r	netatarsal h	nead	Plantar 5 th metatarsal head			
	Plantar PM	A 4-5		Plantar PMA 4-5			
	Plantar Cub	oid		Plantar Cuboid			
Lunge test	<35 Degree	S		<35 Degrees			
	35 Degrees			35 Degrees			
	>35 Degree	S		>35 Degrees			
MSRT	1	2	3	1	2	3	
	4	5		4	5		
Jack's test	Positive			Positive			
	Negative			Negative			

Does the patient have a present plantar foot ulcer? Yes No

If yes, please fill out planimetry and ulcer assessment table below.

Planimetry and Ulcer assessment

Investigation	Ulcer 1		Ulcer 2		<u>Ulcer 3</u>	
Ulcer Location						
Estimated duration of						
ulcer						
In weeks						
Planimetric depth						
cm3						
Planimetry						
Length cm	Length	cm	Length	cm	Length	cm
Width cm	Width	cm	Width	cm	Width	cm
Area cm	Area	_cm	Area	_cm	Area	_cm
Wound exudate/	Mild	Serous	Mild	Serous	Mild	
discharge present	Moderate		Moderate	Purulent	Serous	
and type of exudate	Purulent		High		Moderate	
	High		Haemoserous		Purulent	
	Haemoserous				High	
					Haemosero	us
UTWCS Grading						

Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

Married David	Niconstin	Nametia	NI	
Wound Bed	Necrotic	Necrotic	Necrotic	
	Granulating	Granulating	Granulating	
	Epithelializing	Epithelializing	Epithelializing	
	Sloughy	Sloughy	Sloughy	
	Pale	Pale	Pale	
	Hypergranulating	Hypergranulating	Hypergranulating	
	Bone	Bone	Bone	
Wound Edge	Regular	Regular	Regular	
	Irregular	Irregular	Irregular	
	Undermined	Undermined	Undermined	
	Rolling	Rolling	Rolling	
Sinus Formation	Yes No	Yes No	Yes No	
Yes No	mm	mm	mm	
			_	
Is the ulcer infected?	Yes	Yes	Yes	
-Conduct Wound				
Swab for presence of	No	No	No	
pathological				
microbes.				
Type of organism				
causing infection (As				
per pathology test)				
Type of ulcer	Neuropathic	Neuropathic	Neuropathic	
1	Neuropatriic	Neuropatriic	Neuropatriic	
(Neuropathic,	Neuroischemic	Neuroischemic	Neuroischemic	
Neuroischemic)				
Surrounding Skin	Macerated	Macerated	Macerated	
	Hyperkeratotic	Hyperkeratotic	Hyperkeratotic	
	Indurated	Indurated	Indurated	
	Normal/healthy	Normal/healthy	Normal/healthy	
	Fragile	Fragile	Fragile	
	Erythematous	Erythematous	Erythematous	
	Oedematous	Oedematous	Oedematous	
	Anhidrotic	Anhidrotic	Anhidrotic	
Orthoses Used?	Yes No	Yes No	Yes No	
Offloading shoe or	Yes No	Yes No	Yes No	
boot-walker used?				
Type of Off-loading	TCC	TCC	TCC	
Device	Foot Orthoses	Foot Orthoses	Foot Orthoses	
	AFO	AFO	AFO	
	Padding	Padding	Padding	
	No offloading	No offloading	No offloading	

	Diabetes and	root diceration Study			
Unique Identification Number:	UR:	Name:			
DOB:	Initials:				
How often is the					
ulcer seen by a hea	lth				
professional in a					
month? (X 3)					
month: (x 3)					
How often is the					
ulcer dressing					
changed per month	1?				
(x 3)					
What type of shoe do you currently use most of the time? 1. Sports 2. Dress 3. Diabetic special shoe 4. Custom made shoe 5. Thongs 6. None On average per week how many days do you use this shoe? Days out of seven? /7 Do you wear orthoses? Yes No Custom Off-the shelf Note Quality of life questionnaire to be handed to the patient at this point to fill out then the details and dates for gait assessment visit and follow-up visit on a follow-up card should be given to the patient. Contact details are then recorded separately.					
Pedometer Given to Patient? Yes No Blood Collection – Pathology Refer patient to SNP pathology for blood collection.					
		attiology for blood collection.			
Blood collection form	i giveri to patient?	□ Yes □ No			
		1			

	Diabetes and 100			
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			
		<u> </u>		
Date of Collection		/(dd/mm/yyyy)		
Haemoglobin □□□g/L	-	LD □□□U/L		
WCC □□.□10 ⁹ /L		Cholesterol □.□mmol/L		
Platelets □□□10 ⁹ /L		Triglyceride □.□mmol/L		
Fibrinogen □.□□g/L		HDL □.□mmol/L		
Sodium 🗆 🗆 mmol/L		LDL □.□mmol/L		
Potassium □.□ mmol/	L	CRP □□□mg/L		
Urea □□□ mmol/L		Chloride 🗆 🗆 mmol/L		
Creatinine □□□ µmol,	/L	Bicarbonate □□mmol/L		
eGFR 🗆 🗆 mL/min/1.	73m²	Calcium □.□□mmol/L		
Fasting Glucose □□.□	μmol/L	Phosphorus □.□mmol/L		
HAB1C	%	Total protein □□g/L		
CRPmg/	L	Hematocrit □.□□mg/dL		
ESRmm	n/hr	Neuts □.□10 ⁹ /L		
Parathyroid Hormone	pg/ml	Lymphs □.□10 ⁹ /L		
N-(carboxymethyl) lysine (CML)		Monos □.□10 ⁹ /L		
Non-CML advanced glycation end products (AGEs)		Eos □.□10 ⁹ /L		
Pentosidine		Baso □.□□10 ⁹ /L		
Homocystine				

Vascular Biology Unit Blood Sample Storage Form

Diabetes and Foot ulceration Study						
Unique Identification Number:	UR:			Name:		
Number:						
DOB:	Initia	ls:				
Blood Collection -Fo	r VBI	U Biomarker S	Staf	f to complete		
Has blood been colle		•		Yes	No	
analysis? (Check with	SNP	and Ratnesh)		□ res □	INO	
Date of Collection				(dd/mm/yyyy)		
2 x SST				☐ Yes ☐	No	
2 x EDTA				☐ Yes ☐	No	
1 x Sodium Citrate				☐ Yes ☐ No		
Sample Storage						
Have study bloods be	-			☐ Yes ☐ No)*	
and stored according	to th	ne lab		*If NO, record a Protocol De		
manual?						
Date of Processing			L		(dd/mm/yyyy)	
		Number of Samples:	Н	ave samples been stored at the Protocol defined temperature?	Location of Samples	
Serum					Box#	
(from SST tubes)		(Store at -80°C)	*	☐ Yes ☐ No* f NO, record a Protocol Deviation	Position #	
EDTA Plasma					Box#	
(Purple top EDTA tubes)		(Store at -80°C)	*	☐ Yes ☐ No* f NO, record a Protocol Deviation	Position #	
EDTA RBC Pellet			Box#			
(Remaining pellet from E tubes with plasma remov		(Store at -80°C)	*	☐ Yes ☐ No* f NO, record a Protocol Deviation	Position #	
Citrate Plasma				No.	Box#	
(Blue top Citrate tubes)		(Store at -80°C)	*	☐ Yes ☐ No* f NO, record a Protocol Deviation	Position #	

Diabetes and Foot ulceration Study			
Unique Identification Number:	UR:	Name:	
DOB:	Initials:		

Additional Biopsy Procedure Documentation Sheet-

Foot ulcer patients only as clinically required.

Has informed consent been obtained for biopsy? Yes No

Has VBU staff been advised about time of biopsy collection? Yes No

Appropriate transport medium organised? Yes No

Doctors Statement

I have explained

- The patient's condition
- Need for the biopsy
- The procedure and the risk
- Relevant treatment options and their risks
- Likely consequences if those risks occur
- The significant risks and problems specific to this patient.

I have given the patient/substitute decision maker an opportunity to

- Ask questions about any of the above matters
- Raise any other concerns

Which I have answered as fully as possible. I am of the opinion that the patient/substitute decision maker understands the above information.

Name of Doctor		
Designation		
Date		_
Signature	_	

Biopsy Sample appropriately stored at the VBU? Yes No

Date of storage of Sample-

Part 2: Gait, Pressure and Biomechanical Assessment.

		d Foot ulceration Stu	dy	
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			
Site- 1	ames Cook U	niversity Gai	t Lahorat	nrv
		inversity, dar	<u>c Laborae</u>	. <u>01 y 1</u>
Physical Measurer				
ASIS Breadth	cm	Mass:	\square \square kg	
Left Leg length	cm	Height	cm	
Left Knee diameter	r cm			
Left malleolus widt	ch cm			
Right Leg length	cm			
Right Knee diamet	er cm			
Right malleolus wid	dth cm			
Testing protocol				
Testing protocol				
Measure up:				
EMG prep:				
MVC:				
Reflective markers	prep			
Static capture				
10 walking trails				
Treadmill walking	4 minutes			
(Capture only 2:00				
Self-Selected Walk	ting Speed		km/hr.	
Plantar pressure ca	pture (3 walks)			

FINISHED

Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

Primary Outcome	<u>Measurement</u>	Left	Right
measure	Medial Heel-		
Peak plantar pressure	Lateral Heel		
(N/Cm2)	Medial Forefoot		
(IV/CITIZ)	Lateral Forefoot		
Pressure time	Medial Heel-		
integral	Lateral Heel		
(N/Cm2) X s	Medial Forefoot		
(N) CITIZ) X 3	Lateral Forefoot		
Time of peak	Vastus Lateralis		
occurrence	Lat		
EMG (%)	Gastrocnemius		
	Tibialis Anterior		
GRF	Vertical		
(N/Kg)^D	Med/Lat		
, 3,	Ant/Post		
Oxford Foot	Hindfoot Sag		
Model	Hindfoot Fron		
(deg)	Hindfoot T.V		
	Forefoot Sag		
	Forefoot Fron		
	Forefoot T.V		
Lower Limb	Stance Phase		
Kinematics	Max hip Flex		
	Max hip Ext		
	Max Knee Flex		
	Max Knee Ext		
	Max Ankle DF		
	Max Ankle PF		
	Swing Phase		
	Swing Phase Max hip Flex		
	Max hip Ext		
	Max Knee Flex		
	Max Knee Ext		
	Max Ankle DF		
	Max Ankle PF		

Data-Sets Post-Data extraction

EMG During Gait Assessment

Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

Maximum Voluntary Contraction

<u>Tibialis</u>	Medial Gastroc		<u>Peroneus</u>	Soleus	<u>VMO</u>	<u>Semiten</u>
<u>Anterior</u>		<u>Gastroc</u>	<u>Longus</u>			
Right						
<u>Left</u>						

<u>(%)</u>	<u>Tibialis</u> <u>Anterior</u>	Medial Gastroc	<u>Lateral</u> <u>Gastroc</u>	<u>Peroneus</u>	Soleus	<u>VMO</u>	<u>Semiten</u>
Peak	Antenoi	Gastroc	Gastroc	<u>Longus</u>			
Activation							
Left							
Right							
<u>Contact</u>							
Left							
Right							
<u>Stance</u>							
Left							
Right							
Toe-off							
Left							
Right							
Swing							
Left							
Right							

Treadmill gait assessment

Assessment	Parameter	Left	Right

Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

Oxford Foot Model (deg)	Hindfoot Sag Hindfoot Fron Hindfoot T.V Forefoot Sag Forefoot Fron	
	Forefoot T.V	
Lower Limb Kinematics	Stance Phase Max hip Flex Max hip Ext Max Knee Flex Max Knee Ext Max Ankle DF Max Ankle PF	
	Swing Phase Max hip Flex Max hip Ext Max Knee Flex Max Knee Ext Max Ankle DF Max Ankle PF	

EMG During Treadmill Gait

Muscle	<u>Tibialis</u>	<u>Medial</u>	Lateral	Peroneus	Soleus	<u>VMO</u>	Semitendinosus
	<u>Anterior</u>	<u>Gastroc</u>	<u>Gastroc</u>	<u>Longus</u>			
<u>Peak</u>							
Activation							
Left							
Right							
MVC							
Left							
Right							
Contact							
Left							
Right							
<u>Stance</u>							
Left							
Right							

	Diabetes and Foot ulceration Study								
	Unique Identi Number:	ification	UR:		Name:				
	DOB:		Initials	:					
T		<u> </u>				<u> </u>	l	<u> </u>	
Toe-off									
Left									
Right									
Swing									
Left									
Left Right Swing Left Right									

Summary of Findings

Is the initial ulcer still present?	YES	NO
Has the ulcer size increased?	YES	NO
Has the ulcer size decreased?	YES	NO
Is there formation of a new ulcer?	YES	NO
Has the ulcer completely healed?	YES	NO
Is there a decrease in glycaemic control?	YES	NO
Is there a decrease in renal function?	YES	NO
Has the patient commenced dialysis?	YES	NO
Is there increased AGE formation present?	YES	NO
Are there differences in the ROM of joints?	YES	NO
Is there deterioration of vascular function?	YES	NO
Is there a deterioration of neurological function?	YES	NO
Has there been a reduction in treatment frequency?	YES	NO
Has there been an increase in treatment frequency?	YES	NO
Was a biopsy conducted?	YES	NO
Is there infection present?	YES	NO
Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR	YES	NO
Is the participant still suitable for the study?	YES	NO
Next visit date provided?	YES	NO

Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

If the participant is no longer suitable for the study, please send a letter of thanks for being involved in the study, otherwise provide date and time of next consultation.

Date and time of next consultation _____

- 1. Blood Collection Form Given
- 2. Questionnaires Collected (4)
- 3. Review-date organised
- 4. Pedometer calibrated and given?
- 5. Instructions given on Pedometer return?

Notes

Diabetes and Foot ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

Is the same ulcer still present?	YES NO
Has the ulcer size increased?	YES NO
Has the ulcer size decreased?	YES NO
Is there formation of a new ulcer?	YES NO
Has the ulcer completely healed?	YES NO
Is there a decrease in glycaemic control?	YES NO
Is there a decrease in renal function?	YES NO
Has the patient commenced dialysis	YES NO
Is there increased AGE formation present?	YES NO
Are there differences in the ROM of joints?	YES NO
Is there deterioration of vascular function?	YES NO
Is there a deterioration of neurological function?	YES NO
Has there been a reduction in treatment frequency?	YES NO
Has there been an increase in treatment frequency?	YES NO
Was a biopsy conducted?	YES NO
Is there infection present?	YES NO
Has haematological status deteriorated critically? I.e Lipid profile, WCC, CRP, ESR	YES NO
Is the participant still suitable for the study?	YES NO
Next visit date provided	

If the participant is no longer suitable for the study, please send a letter of thanks for being involved in the study, otherwise provide date and time of next consultation.

Next consultation visit-

End of Study:

Did the participant complete all aspects of the study?

	Diabetes and Foo	ot ulceration Study
Unique Identification Number:	UR:	Name:
DOB:	Initials:	
Yes		□ No
According t	o the protocol	Participant withdrew*
☐ With proto	col deviations or	Lost to follow-up
violations (ensure the protocol dev		
		Participant deceased
		(ensure an SAE has been recorded & reported)
		Patient declined further involvement*
		Other*
*Comment:		
Has a letter of thanks significant findings?	s been sent to the par	ticipant along with a 1-page summary of
YES		
<u>NO</u>		
	s been sent to the par o the referring practiti	ticipant along with a 1-page summary of oner?
YES		
<u>NO</u>		

Diabetes and Foot Ulceration Study				
Unique Identification Number:	UR:	Name:		
DOB:	Initials:			

Protocol Deviations:

Protocol Deviations:				
Deviation Number	CRF Page Number	Deviation	Recorded by	
1				
2				
2				
3				
4				
4				
5				
<u> </u>				
6				
7				
8				
9				
10				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
	<u> </u>			

Diabetes and Foot Ulceration Study					
Unique Identification Number:	UR:	Name:			
DOB:	Initials:				

End of CRF:

Data collection completed by (Name)				
Signature				
Date completed				
Principle Investigator (Name):				
Signature				
Date				