DIABETES RESEARCH PROJECTS

FOOT ULCERS – Contact Sharon Kempson (sharon.kempson@nhs.net) ext. 5066

CODIFI - INCLUSION	CODIFI - EXCLUSION
- Patient has diagnosis of type 1 or type 2; - Patient has suspected ulcer infection with or without bone infection, based on clinical signs and symptoms using IDSA / IWGDF criteria and the judgement of the investigator; -The clinical plan is to treat the patient with antibiotics for their infected ulcer; -Patient is willing and able and at least 18 years of age at the time of signing the consent form.	-The clinician deems it inappropriate to take a curette sample or a swab sample for any reason; -The patient is unable to give valid or informed consent, or deemed inappropriate by clinician

HEELS - INCLUSION	HEELS - EXCLUSION
- Type 1 or Type 2 Diabetes mellitus; - Age 18 years or over; - Heel ulcer (below the malleoli and affecting the skin overlying the calcaneum) of NPUAP-EPUAP Grade 2-4, present for two or more weeks with a cross-sectional area ≥25mm^2. If there is more than one heel ulcer, only one selected as index; - Subjects are both able and willing to give written informed consent.	- Frailty/disability wherein participation might have an adverse effect on patient well-being; - An off-loading device to be non-removable; - Likely protocol violation due to planned travel; - Those who withhold consent; - Active participation in another study of a wound care product; - The use of topical negative pressure or application of larvae to the index heel ulcer

TYPE 1 DIABETES ONLY – Contact Nick Denyer (nick.denyer@nhs.net) ext. 8640

ADDRESS 2 - INCLUSION	ADDRESS 2 - EXCLUSION
- Participants aged between 5-60 years diagnosed with type 1 diabetes within the 6 months immediately prior to enrolment. Diagnosis will be based on the judgement of the diagnosing clinician OR - Participants must be aged between 5-60 years and be the sibling of a person diagnosed with T1 diabetes. Siblings MUST BE FREE from diabetes	- Children under 5 years - Type 2 Diabetes - Adults aged 16-60 years who are not competent to give consent (Judgement of the clinician)

EXTOD - INCLUSION	EXTOD - EXCLUSION
- Age 16-60 and randomisation within 12 weeks of a clinical diagnosis of T1D; - 90 min. meal stimulated C peptide >200pmol/l; - Positive for GAD islet antibody; - Safe to exercise (determined by lead physician); - Patient not pregnant/planning pregnancy within the timeframe of the study; Patient is able and willing to self-monitor blood glucose and record the results via a multiple dose insulin injection regime	- Patient already undertaking sufficient exercise (determined by IPAQ score – Long Last 7 days self-administered format); - Uncontrolled blood pressure (>180/100 mmHg) - Therapy that affects heart rate (e.g. beta blocker) - Ischaemic heart disease (e.g. unstable angina) - Psychological/physical disease that prevents exercise, or planned major surgery which would prevent exercise for >6 weeks - T2D, or participation in another T1D clinical trial

TYPE 2 DIABETES – Contact Lawrence Phiri (lawrence.phiri@nhs.net) ext. 8640

ELIXA - INCLUSION	ELIXA - EXCLUSION
- Patient experienced an ACS event (i.e. STEMI, NSTEMI or UA) =5 days and ≤12 weeks prior to screening; and discharged from the acute care facility (i.e., emergency room) - Patients with history of T2 diabetes (based on WHO criteria (i.e., fasting venous plasma glucose concentration ≥7.0 mmol/L [126 mg/dL] or 2-hour post-glucose load venous plasma glucose ≥11.1 mmol/L [200 mg/dL], on 2 occasions); - Able to gather written informed consent.	- Patients under 30 years old; - Women of childbearing potential with no effective contraceptive method or Women of childbearing potential; - Patients with Type 1 diabetes mellitus; - Patients who have had CABG or PCI -HbA1c <6.0% or >10.0% measured at screening; -Fasting Plasma Glucose >13.9 mmol/L (>250 mg/dL) measured at screening;

SIGN - INCLUSION	SIGN - EXCLUSION
- Age 18 years and over; - Type 2 treated with 2 or more insulin injections daily OR Type 1 as long as on MDI with bolus injections for >6 months prior to study enrolment - Investigator's opinion that patient is technically capable of using FreeStyle Navigator GM Device; - HbA1c between 7.5 and 12.0% (58 to 108 mmol/mol) for previous test obtained within 6 months prior to point of enrolment.	- Concomitant disease/condition that may compromise patient safety; - Female subject is pregnant/planning to become pregnant within the planned study duration; - Currently using/used a Continuous Glucose Monitoring System within the last 6 months; - Currently using CSII *or* basal/long acting insulin. - Participating in another glucose monitoring device/drug study. - Known allergy to medical grade adhesives