STANDARD OPERATING PROCEDURE

NIHRexe273STARTRIGHT: StartRight Study – Visits 2 & 3 Data Collection & Arrangements for Participant Home Urine Collection & Questionnaire Completion (all recruiting Sites)

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Controlled document

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It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please check the study website (www.diabetesgenes.org/current-research/startright/) or contact the CI's team (rde-tr.DiabetesResearch@nhs.net) to confirm you have the latest version.

DISCLAIMER

This study specific R&D Standard Operating Procedure (SOP) must be followed unless a departmental SOP dictates a different working practice.

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Version History Log			
Version	**Date**	**Author**	**Reason**
1.0	10/08/2017	Anita Hill	*Revisions to reflect updated policy*
2.0	10/08/2018	Anita Hill	*Revision to reflect change to urine collection procedure*
3.0	05/11/2018	Anita Hill	*Revision to incorporate visit 3*

Contents

1. BACKGROUND

It is not always easy for doctors to be able to say for certain what kind of diabetes a person has, particularly in adults aged under 50 where the distinction between the types is less clear. Getting the right diagnosis is important to know what treatment will be most effective; for example patients with Type 1 diabetes need insulin, whereas most patients with type 2 diabetes may be effectively treated without insulin.

The purpose of this research is to determine whether blood tests can help us improve treatment by identifying which patients have Type 1 diabetes, and will need very early insulin treatment, and which patients are unlikely to need insulin treatment at diagnosis. These tests include antibodies against the cells that make insulin (often seen in Type 1 diabetes), and a new test which assesses genetic risk of diabetes.

2. PURPOSE

The purpose of this SOP is to ensure correct and uniform data & sample collection from participants in the StartRight study.

3. SCOPE

This SOP applies to all researchers involved in the follow-up of participants recruited to the StartRight Study.

4. RESPONSIBILITIES & TRAINING

All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP

This procedure should only be carried out by personnel who have undergone appropriate trust, GCP and study specific training.

This procedure should only be carried out by personnel who are appropriately listed on the study specific delegation log, signed off by their PI, in their ISF.

All staff should be aware that local Trust policies and procedures apply when planning and undertaking studies.

This SOP will be circulated to all StartRight study teams shortly after release and will be uploaded to the study website https://www.diabetesgenes.org/current-research/startright/

If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.

5. PROCEDURES

5.1 Equipment

The participant's completed documents from previous study visit(s):
- Participant referral & contact form
- Data Collection Form(s)
- Consent Form

Appropriate IT equipment to scan and email completed study documents to the CI site in Exeter by secure nhs.net email.

5.2 Timing of follow-up contact with participant

- As detailed in the study protocol (item 5.1.4), Visit 2 will be conducted between 10 months and 16 months after Visit 1 and Visit 3 will be conducted between 22 months and 28 months after Visit 1.
- A pre-calculated list of follow-up dates for study participants will be provided to each recruiting site in the format:

Study ID	Earliest Visit 2 or 3 Date (10 or 22 months after visit 1)	Latest Visit 2 or 3 Date (16 or 28 months after visit 1)	Date Visit 2 or 3 completed
SRXXXX	dd/mm/yyyy	dd/mm/yyyy	*Local study team to update on completion of visit 2 or 3*

- Using the information recorded at Visit 1 on the participant referral and contact form and the participant's contact preferences recorded on page 4 of their visit 1 DCF, attempt to make contact with the study participant, by phone or email, as close to (but not prior to) their earliest Visit 2 or 3 date. This will help to ensure that, if there are any delays/difficulties in making contact, a successful contact is made in the required time period

- Clearly record all attempts to make contact with the participant in the space provided on the back of the participant referral and contact form.

5.3 Participant Contact & Data Collection

- Once contact is made with the participant, review the details of the study (as per the current PIS) and re-confirm consent with the participant.

- Ensure the participant is given the opportunity to ask any questions, and that they are happy to proceed with study follow-up.

- Check that the contact details recorded on the Participant Referral & Contact form are still current and record any changes on the visit 2 or 3 DCF.

- Check that the participant's GP is as recorded on the Participant Referral & Contact form and record any changes on the visit 2 or 3 DCF.

- Please ensure you use the current version of the Visit 2 or 3 Data Collection Form (DCF) which will be pre-filled with your 4 digit site ID (e.g. Exeter site ID = EXET) and that you add the participant's study ID (SRXXXX) at the top of all pages.

- Collect all data required to complete the Visit 2 or 3 DCF. If diabetes treatment has changed since the previous visit please ensure that details are recorded together with the start or stop dates as appropriate. If exact date is not known, please record month & year.

5.4 Arrangements for Home Urine Collection & Questionnaires

- Ask the participant if they are happy to provide another home urine sample and complete the questionnaires as per their previous visit(s).

- Explain to the participant that the home urine pack and questionnaires (hypoglycaemia & quality of life) will be sent to them in the post direct from the central coordinating site in Exeter within the next 2 weeks.

- As per previous visit(s), full instructions will be provided in study packs but, in summary, the home urine collection procedure is as follows:

  a. **Collect the urine sample between 1 hour and 5 hours after you have eaten a meal containing a carbohydrate (e.g. bread, cereal, crackers, potatoes, rice, pasta, noodles, biscuits etc.), and within 7 to 10 days following receipt of the pack.**

  b. **Write the date and time of sample collection on both the tube and the form.**

  c. **Post the sample on the day of collection (or the next morning if taken in the evening) as it must reach Exeter within 3 days of collection.**

5.5 Further Participant Follow Up

- Explain to the participant that they will be contacted again in approximately 1 year for their next follow-up visit.
  If the next visit is Visit 3 (approximately 2 years from recruitment) the next follow up will be to collect updated information about their diabetes and treatment and to ask them to provide another home urine sample.
  If the next visit is Visit 4 (approximately 3 years from recruitment) the participant will be invited to attend a research appointment that will also include repeating some of the measures (e.g. weight) and blood sample collection carried out at their original recruitment visit (Visit 1).

- Ensure the participant knows how to contact the study team and ask them to notify you if their contact details change.

- Thank the participant for their time.

5.6 Post Visit Data Collection & Transfer of Data to Exeter

- Ensure that **all** fields on the DCF have been completed and that all requested biochemistry results have been recorded. Cross-check the current diabetes medication with that recorded at the previous study visit (Visit 1 or 2). Ensure that any treatment changes have been recorded correctly, including treatment start and stop dates where applicable.

- Update your Visit 2 or 3 log (referred to in section 6.2 on page 5) with the date on which Visit 2 or 3 was completed.

- Sign and date the DCF and send a scanned copy (in .pdf format) to the StartRight central coordinating team by secure nhs.net email to rde-tr.DiabetesResearch@nhs.net

- **PLEASE SEND COMPLETED DCF TO EXETER WITHIN 5 WORKING DAYS OF VISIT.**

6. RELATED DOCUMENTS

StartRight Study Protocol
StartRight Visit 2 DCF
NIHRexe251STARTRIGHT Visit 1 SOP
StartRight PIS
StartRight Consent
R&D/Study Specific SOPs/S24

Appendix I - DEFINITIONS

GCP	Good Clinical Practice
PI	Principle Investigator
CI	Chief Investigator
SOP	Standard Operating Procedure
DCF	Data Collection Form
R&D	Research & Development
PIS	Participant Information Sheet
GP	General Practitioner
NIHR	National Institute for Health Research
ID	Identifier
ISF	Investigator Site File