Research access to the ADDRESS-2 resource

Summary
The project, An Incident and High Risk Type 1 Diabetes Research Cohort – After Diabetes Diagnosis Research Support System-2 (ADDRESS-2) has objectives to facilitate research into type 1 diabetes (T1D) and to improve access to research opportunities for people with T1D.

ADDRESS-2 is building a resource of children and adults in England and Wales with new-onset T1D (diabetes of less than 6 months duration at the time of enrolment) and their siblings who do not have diabetes. These people have consented to be approached about participating in other T1D research studies and agreed that their data and biological samples may be used in other T1D research.

The ADDRESS-2 resource includes a database of clinical and demographic data, including autoantibody status for 60% of participants and a biorepository of serum, DNA and peripheral blood lymphocytes (PBLs).

ADDRESS-2 participants are good candidates for early intervention and prevention trials for T1D, and for aetiology studies. With the passage of time, participants with T1D become suitable for studies for which a minimum duration of diabetes is required, for example, T1D of at least one year in duration.

This document describes how the ADDRESS-2 resource can be used, the principles governing access, and the processes for requesting access.

Background
ADDRESS-2 is sponsored and coordinated by Imperial College London and funded by Diabetes UK and the Juvenile Diabetes Research Foundation. It is underpinned by the NIHR Clinical Research Network (NIHR CRN), which provides an infrastructure to support the set-up and delivery of clinical research in the NHS across England. Research nurses in the NIHR CRN recruit participants to ADDRESS-2 and collect the study data and biological samples. In Wales, ADDRESS-2 is supported by individual diabetes research teams, or by Welsh infrastructure similar to the NIHR CRN.

ADDRESS-2 was created in 2011 following a proof-of-principle pilot project, ADDRESS. It expanded on the pilot to include the collection of optional blood samples and recruitment of siblings. ADDRESS-2 is running at more than 130 NHS Trusts in England and Health Boards in Wales. The average rate of recruitment is 75 people with new-onset T1D per month. Two-thirds of adults and half of the children are recruited within 12 weeks of diagnosis. On average, 20 unaffected siblings are recruited per month.
Uses of ADDRESS-2

The ADDRESS-2 resource can be used in the following ways:

- To provide feasibility data for T1D studies, for example the number of participants in the database meeting specific criteria, or the average number of participants recruited per month meeting specific criteria.
- To identify candidates for clinical trials and other studies recruiting people with T1D or unaffected siblings, and to contact these people about the trial/study.
- To provide anonymous samples from the biorepository for T1D research.
- To provide anonymous clinical and demographical data for T1D research.

How to access the resource

The qualification criteria and access processes differ for different uses of the resource, as described below. Informal enquiries about any use of ADDRESS-2 can be made to the Study Coordinator via email: address2@imperial.ac.uk, or tel: +44 (0)20 7594 1316.

Feasibility data

Qualification criteria

Feasibility data are provided to commercial and non-commercial researchers, on request, free of charge. Data for commercial organisations can be made available as part of the following NIHR CRN services: early feedback, site identification and site intelligence.

How to make a request

Requests from commercial organisation should be submitted via the NIHR CRN online system: www.submitmystudy.nihr.ac.uk. No site-level or regional breakdown of data is provided for early feedback.

Requests from non-commercial researchers should be made to the ADDRESS-2 Study Coordinator via email: address2@imperial.ac.uk, or tel: +44 (0)20 7594 1316.

Identification of candidates for T1D trials or other studies

Qualification criteria

The principles under which approval may be granted to researchers requesting to use ADDRESS-2 to identify candidates for another type 1 diabetes (T1D) research study follow those of the NIHR Clinical Research Network (NIHR CRN) in governing eligibility for NIHR CRN support (set out in the Department of Health policy document “Eligibility for NIHR Clinical Research Network Support, April 2013”). Studies submitted for inclusion in the NIHR CRN portfolio and meeting the NIHR CRN criteria for support are eligible to use ADDRESS-2.
Studies receiving funding as part of an NIHR Biomedical Research Centre (BRC) / NIHR Biomedical Research Unit (BRU) / NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) or NIHR Patient Safety and Service Quality Research Centre (PSSQC) programme are also eligible to use ADDRESS-2.

Studies meeting the NIHR CRN criteria for support but not included in the NIHR CRN portfolio are considered on a case-by-case basis.

**How to make a request**

Requests should be made using the “Request for access to ADDRESS-2 resource - form” and submitted to the ADDRESS-2 Study Coordinator via email: address2@imperial.ac.uk.

**Assessment process**

The aim is to support all NIHR CRN portfolio studies and those in receipt of NHHR funding that request to use the ADDRESS-2 database to identify candidates.

Studies recruiting people with T1D of one year in duration or less (T1D \( \leq 12 \) m), or recruiting in more than one of the 15 local branches of the CRN (LCRNs), or recruiting unaffected siblings are reviewed by a sub-committee of the Management Committee. This is to verify that the qualification criteria for this use of the resource have been met and to set the order of priority for offering studies to participants matching the search criteria for more than one study. The criteria for prioritising studies are described in the document “ADDRESS-2 prioritisation criteria”.

Under normal circumstances the sub-committee shall consist of the Chairperson, the Chief Investigator and the Study Coordinator. In cases where there is a conflict of interest, studies will be reviewed by additional members of the Management Committee, as required. The Chairperson may opt to consult the Management Committee via email regarding study prioritisation.

Individual ADDRESS-2 sites and LCRNs have access to search their site-level and LCRN-level sections of the ADDRESS-2 database to identify candidates for CRN portfolio studies recruiting in single LCRNs. Local searches are permitted for studies recruiting people with T1D of at least one year in duration (T1D > 12 m) without prior review by the Management Committee on the following conditions:

- that the Study Coordinator is informed of all such searches via the “Request for access to ADDRESS-2 resource – form” so that use of the resource can be tracked
- and each participant’s database record is updated with the details of studies offered and studies joined, to prevent inappropriate contact.

This is to encourage use of the resource to identify candidates for studies in T1D > 12 m recruiting on a local level, for which there is a low likelihood of participants meeting the search criteria for more than one study.

The processes for identifying and contacting candidates are described in the document “ADDRESS-2 identifying and contacting T1D research candidates”.
Analysis of anonymous biological samples or clinical and demographical data

Qualification criteria

Research involving analysis of ADDRESS-2 biological samples or the dataset of clinical and demographical data must also adhere to the principles governing eligibility for NIHR CRN support. If the research is not included in the NIHR CRN portfolio of studies the funding stream will be assessed. If the funding stream does not have NIHR non-commercial partner status, applicants will be asked to provide written confirmation from the Funder and the Sponsor that the research meets the NIHR CRN criteria relating to funding and peer-review, specifically that:

a) the funding was awarded in open competition or the opportunity was available to all qualified researchers (written confirmation required from the Funder)

b) was awarded subject to high-quality peer-review (written confirmation required form the Sponsor)

Consent

The research must also meet the conditions of ADDRESS-2 participant consent:

ADDRESS-2 participants give consent for their data and biological samples (including DNA), and the results from testing their samples to be used in diabetes research that has been approved by the ADDRESS-2 Management Committee and has been given independent ethical approval. Genetic testing is limited to diabetes-related genes. Participants understand that samples and data will be made anonymous before being used by researchers outside the study team unless further consent is sought. Participants understand that researchers could be from outside the UK, and specifically outside the European Union.

Researchers will be asked to provide written confirmation from the Sponsor of the research that it has been approved by an independent research ethics committee, quoting the reference number for the ethical review.

How to make a request

Requests for biological samples with or without accompanying data should be made using the form “ADDRESS-2 application for access to biological samples” and for the dataset only using the “Request for access to ADDRESS-2 resource – form”. These should be submitted to the Study Coordinator via email: address2@imperial.ac.uk.

Assessment process

Requests for biological samples and/or data are assessed by the Management Committee. The application and assessment processes are described in more detail in “Access to ADDRESS-2 biological samples” and “Access to ADDRESS-2 data”.