

INTRODUCTION

This document is the *Manual of Operations (MOO)* for the Type 1 Diabetes Genetics Consortium (T1DGC) study. The T1DGC study is an international effort to identify the genes that affect the risk of type 1 diabetes, and is funded by the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) in the National Institutes of Health, Department of Health and Human Services. Additional sponsors of this international effort include: the Juvenile Diabetes Research Foundation (JDRF); National Institute of Allergy and Infectious Diseases (NIAID); and National Human Genome Research Institute (NHGRI).

The Consortium is comprised of four networks (Asia-Pacific, European, North American and the United Kingdom) and a Coordinating Center at Wake Forest University Health Sciences that oversees the operations of the networks.

Within each network, there exists an infrastructure consisting of a Regional Network Center and individual clinics. The Regional Network Center is responsible for maintaining and supporting the every day operations of the clinics. The Regional Network Center staff sends label sets to the clinic and data enters the information obtained from the clinics. Clinics are in close contact with the Regional Network Center and are responsible for the recruitment and examination (*i.e.*, questionnaires and blood collection) of families who meet the study criteria. Any problems or questions that arise that cannot be dealt with at the clinic level are brought to the attention of the Regional Network Center. In turn, the Coordinating Center is in close contact with the Regional Network Centers. Any problems or questions that the Regional Network Centers cannot resolve are brought to the attention of the Coordinating Center. Both the Coordinating Center and the Regional Network Centers monitor recruitment and overall operations. (See Figure 1 for an overview of the T1DGC study structure.)

Due to the diverse nature of this study, the *Manual of Operations* is web-based in design. When necessary, this document is updated and all revisions are posted on the T1DGC web site. The Regional Network Centers are notified of changes via e-mail,

and are responsible for notifying the clinics. Regional Network Centers are responsible for ensuring that the most current version is used at each clinic, verifying this by noting the date shown on all pages of the document. The Coordinating Center encourages Regional Network Centers to provide hard copies of this document to the individual clinics for their reference, especially if a clinic does not have access to the Internet.

For questions related to this manual, please contact the Coordinating Center at:

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Figure 1. Type 1 Diabetes Genetics Consortium Organizational Chart

